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HEALTH TECHNOLOGY CASE STUDY 36

Effects of Federal Policies on Extracorporeal Shock Wave Lithotripsy

MAY 1986

This case study was performed as part of OTA's Assessment of

Payment for Physician Services: Strategies for Medicare

CONGRESS OF THE UNITED STATES
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Preface

Effects of Federal Policies on Extracorporeal Shock Wave Lithotripsy is Case Study 36 in OTA's Health Technology Case Study Series. This case study has been prepared in connection with OTA's project on *Payment for Physician Services: Strategies for Medicare,* which was mandated by the Deficit Reduction Act of 1984. The House Committees on Ways and Means and Energy and Commerce and the Senate Committee on Finance have jurisdiction over that part of the law. The Senate Special Committee on Aging also requested the study of physician payment.

OTA case studies are designed to fulfill two functions. The primary purpose is to provide OTA with specific information that can be used in forming general conclusions regarding broader policy issues. The first 19 cases in the Health Technology Case Study Series, for example, were conducted in conjunction with OTA's overall project on *The Implications of Cost-Effectiveness Analysis of Medical Technology*. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of cost-effectiveness or cost-benefit analysis, OTA was able to better analyze the potential contribution that those techniques might make to the management of medical technology and health care costs and quality.

The second function of the case studies is to provide useful information on the specific technologies covered. The design and the funding levels of most of the case studies are such that they should be read primarily in the context of the associated overall OTA projects. Nevertheless, in many instances, the case studies do represent extensive reviews of the literature on the efficacy, safety, and costs of the specific technologies and as such can stand on their own as a useful contribution to the field.

Case studies are prepared in some instances because they have been specifically requested by congressional committees and in others because they have been selected through an extensive review process involving OTA staff and consultations with the congressional staffs, advisory panel to the associated overall project, the Health Program Advisory Committee, and other experts in various fields. Selection criteria were developed to ensure that case studies provide the following:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies in different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (e.g., general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (e.g., cost);
- examples of technologies with associated high costs either because of high volume (for low-cost technologies) or high individual costs;
- examples that could provide information material relating to the broader policy and methodological issues being examined in the particular overall project; and
- examples with sufficient scientific literature.

Case studies are either prepared by OTA staff, commissioned by OTA and performed under contract by experts (generally in academia), or written by OTA staff on the basis of contractors' papers.

OTA subjects each case study to an extensive review process. Initial drafts of cases are reviewed by OTA staff and by members of the advisory panel to the associated project. For commissioned cases, comments are provided to authors, along with OTA's suggestions for revisions. Subsequent drafts are sent by OTA to numerous experts for review and comment. Each case is seen by at least 30 reviewers, and sometimes by 80 or more outside reviewers. These individuals may be from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists, sociologists, decision analysts, biologists, and so forth, as appropriate, also review the cases.

Although cases are not statements of official OTA position, the review process is designed to satisfy OTA's concern with each case study's scientific quality and objectivity. During the various stages of the review and revision process, therefore, OTA encourages, and to the extent possible requires, authors to present balanced information and recognize divergent points of view.

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[b] Original publication numbers appear in parentheses.

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[d] Background Paper #3 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[e] Background Paper #5 to *The Implications of Cost-Effectiveness Analysis of Medical Technology*.

[f] Background Paper #1 to OTA's May 1982 report *Technology and Handicapped People*.

[g] Background Paper #2 to *Technology and Handicapped People*.

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Chapter 1

Summary and Policy Implications

Chapter 1

Summary and Policy Implications

INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is revolutionizing the treatment of kidney stones. This technology, which disintegrates stones in the kidney and other upper urinary areas through the use of shock waves, does not require an incision and is immensely attractive to patients who suffer from such stones. Although great uncertainty still remains as to the long-term effects of ESWL treatment, at present it appears to be both effective and highly desirable for many of these patients. Many hospitals and physicians are eager to provide this treatment, and third-party payers of health care are eager to reimburse for it. Yet the arrival of ESWL on the American market has presented a challenge to U.S. health policies and the health care system.

The Federal Government actively influences the development of ESWL technology and its diffusion[1] into the health care system in many ways. Trade policies and monetary policies affect the availability of the Dornier lithotripter, and other ESWL devices manufactured outside the United States, to U.S. hospitals. Science, patent, tax, and other domestic policies affect the willingness and ability of U.S. companies to develop competitive devices. Federal health policies, the focus of this study, govern to a greater or lesser extent the marketing, purchase, payment, and planning for medical technologies. These health policies include the requirements of the Food and Drug Administration (FDA), which affect the manufacture and marketing of ESWL devices. Other Federal health policies relate to the payment and planning for medical services, which affect the acquisition and distribution of the devices.

The lithotripsy device is large and very expensive. It is most comparable in price to major diagnostic imaging equipment. A complete lithotripsy facility, with adjunct cystoscopy rooms, recovery room, and anesthesia capabilities, is comparable to a surgical suite. And a single ESWL unit can serve a large population, analogous to the specialized services of a heart surgery center or a burn unit.

Despite the fact that it is not a "typical" medical technology, ESWL deserves close attention for two reasons. First, it has illustrated a number of ambiguities and problems in the Medicare payment system, and many of the dilemmas it has posed—and still poses—to Medicare also face other third-party payers. These dilemmas may well occur a second time if the technology is successfully extended to treatment of gallstones. Lessons from Medicare's experience with ESWL may also benefit a variety of other medical technologies that, like ESWL, are not easily categorized for the purposes of Medicare payment.

Second, and more importantly, ESWL has great cost-saving potential that may never be realized under current health payment and planning policies. If ESWL is provided in regional centers that are used to capacity, it will cost less per patient to the centers and perhaps to payers than most alternatives. But because ESWL, if available at only a small number of centers, is potentially very profitable to those centers, many hospitals, physician groups, and other organizations wish to be among those who own a lithotripter. ESWL is a very attractive technology to patients, and hospitals and physicians expect to benefit from providing it. Conversely, hospitals without an ESWL unit, and physicians without access to one, expect to lose patients. These circumstances create strong incentives to install and use an ESWL unit, even if competition from nearby ESWL centers means the unit itself will generate little, if any, revenue greater than cost.

This case study analyzes the effects of Federal health policies on ESWL and its integration into the American health care system. As background for this analysis, the study first describes the incidence of urinary stones and the need for stone treatment (ch. 2) and presents a brief overview of the literature on the safety and efficacy of alternative treatments for urinary stones (ch. 3). Chapter 4 reviews the evidence on the safety and efficacy of ESWL itself and discusses the effects of the requirements of FDA on its development. Chapters 5 and 6 describe the costs and economics of providing ESWL and the payment policies of the Federal Government, particularly Medicare, that affect the adoption and use of this technology. Finally, chapter 7 examines the effects of health planning policies on ESWL and discusses its future direction and use.

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[1] The diffusion of a health care technology refers to the extent and manner of its adoption and use by health care providers and patients.

The remainder of this chapter summarizes each of these topics and their implications for Federal policies.

SUMMARY

Urinary Stones

Urinary stones, or calculi, are a familiar phenomenon with known characteristics but with often puzzling origins. Stones of the urinary bladder are common in less developed countries, while stones in the kidney and upper ureter predominate in developed nations. Differences in diet and fluid intake may be partially responsible for this phenomenon. Predisposing factors for developing urinary stones include a past history of stone formation, certain hereditary conditions, and disabilities due to spinal cord injuries (which reduce the body's control over the urinary system). Males and persons of Caucasian ancestry seem to develop stones more readily than others in the population, though this result may obtain partially from sampling error and the fact that men seem to form stones at an earlier age than women.

Although the exact factors that cause the body to alter its metabolic environment are unknown in many cases, several metabolic conditions are correlated with stones. Persons with calcium-containing stones, the most common type, usually have abnormally high concentrations of calcium or uric acid in the urine. Persistent urinary tract infections and the presence of certain conditions and diseases, such as renal tubular acidosis, are also consistent predictors of stones. Medical treatment of metabolic disorders can often reduce the incidence of stone recurrence, and advances in such treatments may affect the number of patients with stones requiring more aggressive treatment.

Urinary stones are quite common. Data on stone incidence in the United States indicate that approximately 3 out of every 2,000 persons annually require hospitalization for urinary stones (196). The rate for men is higher than average, about 2 hospitalizations per year for every 1,000 men in the population; approximately 10 percent of men will form urinary stones at some time in their lives (83). Incidence of stones varies considerably by region, with persons living in the Southeastern United States more likely and those in the West less likely to form stones. There is strong evidence that stone incidence in the United States has increased over time, but whether this trend will continue is still a matter of debate (14).

Estimates of the exact incidence of upper urinary stones in the United States are fundamental to analyses of the impact of stone treatment technologies. Most estimates are from hospital discharge data; these probably underestimate the total number of symptomatic stones, but they may be a reasonable estimate of the number of stones requiring aggressive treatment. The extent of the market for each treatment alternative depends on the extent to which stones that could be treated less aggressively are considered eligible for that treatment. It also depends on the extent to which the alternative is applicable to stones other than upper urinary stones, particularly stones in the lower urinary tract and the gall bladder.

Alternative Treatments for Urinary Stones

ESWL aside, physicians' options for treating and preventing urinary stones have greatly expanded in recent years. Patients with very small stones, which may pass out of the body without assistance, are commonly treated with pain medication and high fluid intake. Prevention of stones can also be accomplished in many instances with careful diet and a small but growing number of drugs that can help reduce stone recurrence. The willingness of a patient to comply with a long-term strict dietary regimen, however, may be a limiting factor in prevention.

Surgical procedures have been standard treatment for problematic urinary stones for some time. Although traditional open kidney surgery is usually successful, it is associated with a significant risk of complications, and successive surgeries can eventually damage or destroy a kidney. Due to the great expansion in alternative techniques, open surgery is now on the decline, though it will continue to be the treatment of choice in a small proportion of cases not suited to other approaches.

Transurethral[2] manipulation of stones can often be used to extract lower urinary stones without an incision, as instruments are passed up the urethra to the bladder and lower ureter. Simple catheterization (insertion of a tube up into the urinary tract) may also induce a stone to pass. Transurethral manipulation, and particularly catheterization, is frequently used in conjunction with ESWL.

Percutaneous procedures, which require only a small incision and an established passageway to the stone through the intervening flank tissue, are a recent addition to the urologists' armamentarium. They carry about a 4-percent risk of significant complications (166). Their benefits over traditional open surgery include reduced hospitalization and convalescence and, in most cases, less expense. Percutaneous fragmentation and extraction of stones is sometimes performed either before or after ESWL for very large renal stones. Its use, either alone or in combination with ESWL, has increased dramatically in recent years and is still expanding rapidly.

A variety of tools are available to fragment and/or extract stones in either transurethral or percutaneous procedures. Mechanical crushers have been used but are rare; special forceps and baskets to extract stones are much more common. Dissolution of stones through prolonged direct application of drugs has also been used but is not widely accepted. Combination therapy of dissolution treatment and ESWL has been tried (149).

Two methods of fragmenting and removing stones with power tools are electrohydraulic and ultrasonic lithotripsy. Both tools are incorporated into probes that are inserted to the point of the stone. Electrohydraulic lithotripsy, which relies on shock waves produced by a spark to fragment stones, has been most successful in transurethral removal of bladder stones (108). Ultrasonic lithotripsy, in which the fragmenting energy is produced by an ultrasound device, has been more commonly used in percutaneous treatment of renal stones. Other power lithotripters, utilizing laser energy or microexplosion techniques, are currently under investigation but are not approved for marketing in the United States.

ESWL: Efficacy, Safety, and Regulation by the Food and Drug Administration

ESWL is a very new technology with characteristics unlike any other treatment for stones. Approved by FDA only since December 1984, for treatment of upper urinary stones, the Dornier lithotripter uses shock waves produced outside of the body to fragment stones without an incision. Stones are pinpointed during the procedure by an X-ray system that is part of the device. Only one manufacturer, Dornier Medical Systems of West Germany, presently has FDA approval to market the device, but several other companies around the world are developing their own models.

Despite concern in animal trials about damage to lung and other tissue, experience with ESWL thus far demonstrates a very low rate of complications with the procedure.[3] The most common

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[2] This study includes as transurethral procedures those procedures that are transureteral as well, i.e., require that instruments be passed through the urethra and bladder and up into the ureter.

[3] Two patients have died under circumstances associated with ESWL. One patient died of a heart attack during the procedure during clinical trials of an early ESWL device model in West Germany. However, the cause of the heart attack was determined not to be related to the application of shock waves. The second patient, a U.S. patient about to undergo ESWL, died of anesthesia complications in 1985 (203).

Photo credit: Dornier Medical Systems, Inc., Marietta, GA

As of April 1986, Dornier Systems of West Germany was the only manufacturer of ESWL equipment with approval to market the technology.

side effects of ESWL are pain and bloody urine; the former is treated with medication in about two-thirds of patients in the United States undergoing ESWL, and the latter usually resolves without treatment. Radiation from ESWL is higher than that from X-rays associated with standard open surgery but lower than that from percutaneous procedures.

Since the Dornier lithotripter was a new device, substantially different from any technology marketed before 1976 (when the Medical Device Amendments were enacted), the lithotripter had to obtain FDA approval before it could be marketed in the United States. While awaiting approval, the device underwent clinical trials at 6 U.S. hospitals to support data from over 2 years of clinical trials in West Germany. Approval was granted in December 1984, 10 months after the first ESWL device was installed in the United States.

ESWL has already emerged as the preferred treatment among many urologists for most upper urinary stones. It is estimated to be effective, alone or in combination with other therapies, in treating up to 95 percent of the patients for whom it is used, and the majority of patients treated with ESWL show no signs of stones 3 months later. As many as one-quarter of ESWL patients may require repeat or adjunct procedures; these patients often have stones that are large, located in the ureter, or accompanied by a urinary tract infection. Over 50,000 people worldwide had been treated with ESWL as of October 1985 (81), and the number has increased substantially since.

ESWL technology has continued to advance at a rapid pace. At least three American manufacturers are developing their own ESWL devices, although as of December 1985 only one had received permission from FDA to begin clinical trials. At least one French device is also in clinical trials in France. It is unlikely that any devices competing with the Dornier lithotripter will be available on the U.S. market before the end of 1986. Dornier itself is developing an ESWL device that will fragment gallstones; the device has begun clinical trials in West Germany.

The impact of Federal premarket approval policies may be felt by manufacturers developing ESWL devices to compete with the Dornier device. Some of the alternative devices being developed are significantly different from the Dornier device in the source of the shock wave, the path through which it travels, and the imaging system. Although manufacturers would probably undertake substantial clinical testing of new ESWL devices in any case, for marketing purposes, FDA requirements for testing and data collection will probably encourage more rigorous and extensive testing than would otherwise have been done. These requirements will help ensure the safety of new ESWL devices, but an unintended effect of premarket approval policies may be to retard the speed with which competitors can get their devices to market to compete with the Dornier device.

The Costs and Economics of ESWL

An important characteristic of ESWL is that it is very costly to purchase but can save overall medical expenditures if used efficiently. In 1985, the cost of purchasing and installing a Dornier lithotripter was approximately $2 million, depending on the exchange rate and on extent of renovation and building needed for the facility. Manufacturers of alternative extracorporeal lithotripters under development report anticipated purchase prices of $400,000 to $850,000 for their devices; how these devices will compare in quality to the Dornier device is still unknown. The costs of operating a lithotripter will probably vary less among upcoming and established models. The most likely source of future variations in operating cost would be the development of a longer lasting and less expensive power source for the shock wave. Because of the high fixed costs of performing ESWL, per-patient costs decline dramatically as the number of patients treated increases.

The high fixed costs of ESWL, combined with its use for a single, definable population (those with urinary stones), make this technology one that may be most appropriately and efficiently provided in a few regional centers. Observers have predicted a "need" for ESWL of as few as 17 units (155) and as many as 175 units (11), depending on how many urinary stone patients are assumed eligible for the treatment and how many patients per year each unit treats. Dornier had already installed 50 ESWL units by the end of 1985 (125), equal to the median estimate of units "needed" as calculated by the Blue Cross and Blue Shield Association (14). The attraction of this technology to patients, and thus to providers, has generated concern that hospitals and other purchasers may overpurchase ESWL units, leading to higher costs to payers and to the ESWL centers themselves.

The cost to physicians of performing ESWL is difficult to define, because of the problem in valuing time and experience.[4] Physician charges for ESWL, approximately $1,800 to $2,000 for single treatments, have been based on their charges for open surgery. However, ESWL will probably be less expensive for physicians to perform than open surgery or percutaneous lithotripsy in the long run, because it appears to require less physician time. If payments to physicians for ESWL are equivalent to those for invasive procedures, physicians are likely to have strong financial incentives to gain access to, and perform, ESWL. These incentives are strengthened by the attractiveness of ESWL to patients, who may seek out physicians performing the procedure.

An attractive feature of ESWL is the potential for minimizing or eliminating hospitalization. ESWL is being performed on ambulatory patients at some centers where patients have adequate medical and social support, such as easy and rapid access to urgent care services for pain medication. Another important consideration for patients is the short recuperation time from ESWL. Most patients can return to normal activity in less than a week of the procedure, minimizing work time lost. Alternative surgical technologies for removing stones can involve back-to-work delays as short as 1 week (for percutaneous lithotripsy) and as long as 6 weeks (for open surgery) (129,170).

Comparing total institutional and professional costs of alternative treatments for upper urinary stones is difficult because no studies of the range of alternatives available have been performed on randomly chosen or well-matched patients. Independent studies of total historic charges in two hospitals, however, combine to suggest that ESWL is usually less expensive than alternatives when performed alone. Reported charges indicate that one-stage percutaneous procedures may sometimes be less expensive than ESWL, but since neither institution performed both procedures, this conclusion is a tenuous one. Total charges for stone removal and associated hospital services in these studies were higher for open surgery than for either ESWL or most percutaneous methods.

ESWL and Federal Payment Policies

Federal payment policy exerts its greatest influence through the Medicare program, both because of Medicare's actual payment methods and levels and because it is often a model for State and private payment for health care services. Medicare has covered ESWL provided in hospitals since March 15, 1985.

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[4] The distinction between costs and charges is often unclear in the medical literature. "Costs," as used here, refers to resource costs of the provider of services. These are inputs such as physician time, labor and administration costs, construction and depreciation, and the costs of medical devices and drugs. "Charges," on the other hand, are essentially "list prices" assigned by the provider (53). Because a provider may charge more than its costs for one service to make up for losses in another service, charges are not necessarily directly related to costs.

Medicare payment for the operating costs incurred by hospitals for inpatients is made under the Prospective Payment System (PPS), which pays a set rate for each of 469 diagnosis-related groups (DRGs). Because ESWL is unlike any current invasive procedure, its use as the sole procedure places a patient in one of two DRGs that include most medical treatment for upper urinary stones. These DRGs pay considerably less than do the DRGs for surgical treatment for urinary stones, and thus the payment a hospital receives for providing ESWL is considerably less than the payment it would receive for providing surgery. Payment for these medical DRGs is likely to cover actual operating costs for a patient only if that patient has a short hospital stay and if the hospital is very efficient, treating a large number of ESWL patients.

Capital costs are not incorporated into PPS, but are paid by Medicare according to its share of those costs. At present the capital costs of purchasing an ESWL device are quite large, and if capital costs become reimbursed as some percentage increase in current DRG payments (as has been proposed), the DRG payment might not cover ESWL costs even for hospitals providing ESWL efficiently. The extent to which this payment system would discourage purchase of ESWL devices depends on the mechanisms used by hospitals to evaluate capital investments and the development of less expensive ESWL devices.

Medicare will pay for ESWL provided to hospital outpatients but not for the facility costs of ESWL provided in other ambulatory centers. Experience with ESWL provided to ambulatory patients is small but growing. If ambulatory ESWL becomes widely accepted, there are likely to be incentives for hospitals to encourage physicians to treat patients as hospital outpatients, since payment for these services is currently based on the costs of providing the services rather than on a DRG rate. Coverage of ESWL provided in ambulatory surgical centers (ASCs) requires a separate decision by the Health Care Financing Administration (HCFA) to include ESWL on the list of procedures payable by Medicare in this setting. Even if ESWL were covered in ASCs, however, these facilities would have little financial incentive to perform ESWL on Medicare patients at current Medicare payment rates for procedures in this setting; the highest ASC payment rate for a single procedure is $336.

The issues ESWL raises regarding Medicare physician payment are somewhat different from those regarding hospital and ASC payment. Medicare pays physicians the "approved charge" for covered services, an amount calculated from the actual and historical charges for each service. Because ESWL is a new technology, there is no charge history for it. Some urologists have argued that performing ESWL should be reimbursed at the same rate as performing surgery for upper urinary stones. Medicare carriers in the first States with ESWL have generally chosen to reimburse at a level slightly below this rate; HCFA is suggesting that a reasonable rate for the procedure may be quite a bit lower than charges for surgery. A problem with the current Medicare payment method is that, although the costs of performing a new procedure often decline over time, charges tend to remain at initial high levels or rise. Alternative payment methods currently under discussion, such as fee schedules, payment for packages of services, and capitation payment, might provide a context for more systematic reevaluation of payment rates. Alternatives in which physician payment rates are unchanged by the treatment chosen, such as capitation payment, might also promote the least costly of the range of appropriate treatments for any given patient.

Federal payment policies can have a substantial effect on ESWL. Although Medicare patients are a minority of those persons who have stones, these patients may be more likely than younger or more able-bodied persons to be recommended for ESWL treatment because Medicare patients are at a higher risk of complications from surgery. Medicare policies, through the level of payment for ESWL treatment, can have a significant impact on patient access; high payment levels might encourage hospitals to provide the technology, while low levels might discourage purchase of ESWL units and the provision of ESWL services to Medicare patients. However, high hospital payment levels could also encourage the overpurchase of ESWL units, driving the costs of treating each patient upward because the purchase cost of each unit would be distributed across only a few patients. Furthermore, under Medicare's current physician payment method, initial payments to physicians that are comparable to rates for surgery may encourage provision of ESWL to Medicare patients, but such payments have tended to remain high even after costs declined and a technology was widely provided. A payment method that incorporated subsequent review or occasional renegotiation of prices, such as through contracting with individual ESWL centers for the care of Medicare patients, would be more successful at reducing payments as costs declined.

The Veterans Administration, the Department of Defense, and the Indian Health Service (IHS) are also significant Federal purchasers of health care. The Veterans Administration is installing one donated Dornier lithotripter and plans to purchase two or three more in the near future, to be situated at centers serving a high number of spinal cord injury patients (102). The Department of Defense operates military hospitals through its Armed Services branches. It has not yet purchased a lithotripter. IHS similarly operates a number of hospitals for its own client population. Its hospitals, however, are primarily small rural ones; none now owns a lithotripter and none is likely to acquire one in the near future. In some areas, IHS also contracts for certain services that are available in community hospitals but not in IHS hospitals. Where urgent stone treatment is such a service, an IHS beneficiary might have access to ESWL if the contracting community hospital provides this service.

The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), operated by the Department of Defense, provides health insurance for dependents of active members of the Armed Services, for retirees, and for the dependents of retirees. Although CHAMPUS provides strong incentives for its beneficiaries to receive care at military hospitals, beneficiaries may in some cases also be reimbursed for care in the community. CHAMPUS pays for physician services on the basis of "reasonable" charges and is currently paying the charges submitted by physicians for ESWL until it has a sufficient experience with these charges to do otherwise (69).

Effects of Federal Policies on Planning for ESWL

The Federal Government affects health care planning both indirectly, through payment policies, and directly, through planning regulation and funding. It regulates the acquisition of major medical equipment in two ways: through the section 1122 provision of the Social Security Act (Public Law 92-603) and through the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). Section 1122 permits the Department of Health and Human Services to enter into voluntary agreements with States. These agreements allow Medicare and Medicaid to withhold certain capital-related payments for patient care in which major medical equipment was used if the acquisition of that equipment was not approved by a State planning agency. If a State certificate-of-need (CON) law is in effect, section 1122 is largely redundant. However, unless capital costs are incorporated into PPS by October 1986, or Congress passes some alternative legislation, section 1122 review will become mandatory in every State, providing Medicare with potential grounds for denying capital payments for ESWL in some cases.

The Health Planning Act required States to pass regulatory planning laws in order to receive certain Federal health-related funds. These State CON laws were to require all hospitals and other specified institutions wishing to add facilities or acquire major equipment to receive prior approval from a State planning agency. Some States regulate the acquisition of certain medical equipment by physicians' offices as well. In recent years Federal enthusiasm for the State CON programs has waned, and the penalizing provisions of the Health Planning Act have not been enforced.[5] As of December 1985, eight States had no CON program at all.

CON laws in the past have not been found to be particularly successful at restricting acquisition of expensive equipment. They are unlikely to be sucessful overall in preventing overpurchase of ESWL, but in a few cases the State planning process seems to be facilitating some innovative arrangements to share the technology. The local planning and purchasing arrangements for ESWL are enormously varied. In some areas, such as Ohio, the existence of CON laws seems to encourage hospitals and physicians to share the purchase and provision of a single ESWL unit (113). In other areas, such as southwestern Pennsylvania, health planning agencies have been unsuccessful at encouraging sharing (36). Instead, agencies are rationing permission to acquire ESWL by approving only one or two applications in order to discourage overpurchase, awarding lucrative near-monopoly rights to those centers. Still other areas, such as Chicago, are apparently unable to limit the number of ESWL units even in this way.

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[5] On Feb. 4, 1986, the House of Representatives passed a bill (HR 3010) reauthorizing financing for health planning but terminating such funding after the current fiscal year, which expires Sept. 30, 1986.

Planning for ESWL and anticipating its future are complicated by the existence of a market that is changing on five fronts:

1. advances in preventive technologies for urinary stones,
2. improvements in invasive treatments,
3. emergence of devices competitive with the Dornier lithotripter,
4. greater experience in using ESWL, and
5. modifications in the Dornier lithotripter itself.

Of these, improvements in invasive treatments and increased experience in the use of the Dornier lithotripter will have the most immediate effects. Competitive devices and extended applications of the Dornier lithotripter may exert some effect on the market in a year or two. Preventive technologies could have major effects, but their impact is neither certain nor imminent.

CONCLUSIONS

The available evidence to date suggests that, relative to alternative invasive technologies, ESWL for upper urinary stones is equal or better on safety and efficacy grounds, when performed by an experienced physician in a hospital setting. The rapid expansion of the technology into ambulatory settings offers opportunities to provide ESWL at lower cost than at present. However, safe ambulatory ESWL requires the availability of transportation to appropriate emergency care after the patient leaves the ESWL center, as well as appropriately coordinated followup care by the patient's own urologist. Ambulatory treatment will not be appropriate for many patients who lack access to these services, and its quality compared to the quality of ESWL in inpatient settings has not yet been thoroughly evaluated.

Considerable research remains to be done regarding the appropriate use of ESWL instead of, or in conjunction with, endoscopic procedures for upper urinary stones. Percutaneous lithotripsy has evolved very rapidly, side by side with ESWL, and is being performed in some centers with results comparable to those obtained with ESWL, at comparable cost. As ESWL is applied to lower urinary stones, the appropriate use of ESWL vs. transurethral procedures will also become an area requiring clinical scrutiny. In any case, evidence suggests that open surgery is no longer the most appropriate treatment for most urinary stone patients.

Substantial uncertainty regarding the long-term use of ESWL remains. ESWL as currently performed includes significant ionizing radiation; the development of high-resolution ultrasound imaging equipment may reduce this potential long-term danger. More difficult to assess are the implications of any renal damage that might develop in the long run for patients who undergo repeated ESWL for stones, or a single procedure with a high number of shock waves. No evidence regarding this potential danger exists.

The United States may house enough Dornier lithotripters to serve the domestic population by the time other manufacturers can bring their devices to market; indeed, by some calculations, the necessary number has already been reached. More devices will improve patient access, but they will also raise both the costs to hospitals (and other centers) of treating each patient and, under current payment arrangements, most likely the expenditures of payers. Conversely, localization of ESWL to a few regional centers may lower per-patient cost but implies more difficult access to those patients living at great distance from these centers. As with any expensive and sophisticated technology, this problem will be especially acute for rural inhabitants, such as many American Indians, since small rural hospitals (including IHS hospitals) will not be able to afford or justify acquiring ESWL capabilities.

Hospital managers and physician groups may urge the purchase of ESWL units despite the problems that may be encountered with oversupply of the service, particularly if the payment rates of Medicare and other payers are generous. On the one hand, if a facility acquires an ESWL unit in an area that produces a sufficient stone population to support the unit, that facility will reap both prestige and profits. Furthermore, by not acquiring the device, a facility may lose a significant proportion of its patients to other facilities in the area that do provide ESWL. Hospitals may wish to acquire ESWL because they compete for patients directly, and because they compete for physicians as a way of drawing the patients referred by those physicians. These considerations are strong incentives to purchase the machine, despite the fact that if many facilities in one area provide ESWL, they will all have small caseloads and consequently high costs and low profits or losses. Furthermore, these incentives operate to some extent even if payment rates are low, exacerbating the low or absent actual financial gains. In theory, either payment or planning policies could prevent overpurchase of ESWL and assure a distribution of units consistent with population size and stone incidence. In practice, neither will probably fully achieve these goals.

Finally, the combination of payment and planning effects may have a significant effect on the urology specialty. In any community in which not all urologists have access to, or are trained to use, ESWL, the urologist to which a patient is referred may have a strong influence on the treatment received. Urology may develop a "subspecialty" of those physicians who can perform ESWL and have access to ESWL units. Such a development could have positive implications for the quality of care afforded those patients receiving ESWL, since their ESWL physicians would be highly experienced. However, it might result in great variations in treatment for the same indications, if urologists who do not have access to ESWL units are reluctant to refer their patients to urologists who do. The incentives would be for urologists without access to ESWL to underprescribe this treatment for their patients, perhaps by routinely performing surgery on younger patients with first stones. Conversely, urologists with access to ESWL would have an incentive to overuse it, perhaps by recommending the procedure when medical treatment might be sufficient.

Universal access of urologists to ESWL is no panacea, however. In areas where a large number of urologists have access to an ESWL center, patients have the greatest potential access to ESWL through their urologists but could receive lower quality treatment if each urologist does ESWL only a few times a year and is consequently less proficient at the procedure.

ESWL exemplifies the service specialization and regionalization of tertiary care, as "stone treatment centers" specializing in urinary stone care proliferate. The lessons learned from current payment and planning experiences may well be applicable again as ESWL technology is turned toward treatment of gallstones, involving an entirely new set of physicians and other providers and requiring new payment levels and a new assessment of the appropriate role for ESWL. The fact that ESWL for gallstones is likely to require a dedicated device, at least in the short term, suggests that its diffusion may parallel that of ESWL for urinary stones.

Chapter 2

Urinary Stones

Chapter 2

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INTRODUCTION

Urinary stones are by no means a modern affliction. One stone was detected in a 7,000-year-old Egyptian skeleton (136), and infection-induced stones were familiar to Hippocrates (67). The long history of urinary stones, however, has not been accompanied by a thorough understanding of their underlying causes. Today, technologies to treat the most common kinds of urinary stones are far ahead of techniques to identify those individuals at risk and to prevent initial stone formation. One of the best predictors of urinary stone formation is still a history of urinary stone disease in the past.

The crystalline concretions known as stones (or "calculi") can occur in many parts of the body besides the urinary tract. It has been estimated, for instance, that 15 million Americans harbor gallstones, although most of these stones are asymptomatic (66). Calculi also appear in joints and in such diverse organs as the prostate and mammary glands. Urinary stones, however, are the only ones widely amenable to extracorporeal shock wave lithotripsy (ESWL) at present, and they are thus the focus of this chapter.

Although urinary stones have been present for thousands of years, industrialization seems to have affected the locations in the body where stones tend to form and the distribution of urinary stones in the population. Bladder stones are common in developing countries and rare in industrialized nations; the converse is true for kidney and ureteral stones. Affluence and male sex have been associated with an increased risk of stone formation, but the reasons are not clear. Dietary changes (increased protein) and decreased fluid intake are attractive, but unproven, hypotheses that may partly explain the observed associations with stone disease (33). Hereditary factors may also be an important predictor of the risk of developing urinary stones (44), but again the precise mechanisms that lead to stone formation are, for the most part, poorly understood.

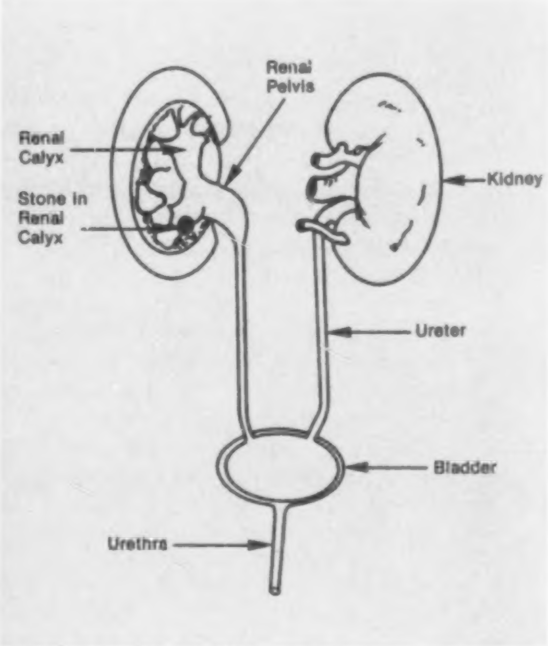
This chapter briefly reviews the structure and function of the urinary tract and the types of stones that occur. It then presents estimates of upper urinary stone incidence in the U.S. population and summarizes current thinking regarding the distribution, causes, and predictors of upper urinary stones, those most amenable to ESWL treatment. It concludes with a brief discussion of the applications and limitations of these estimates of stones and stone recurrence as they apply to discussions of ESWL.

STRUCTURE AND FUNCTION OF THE URINARY TRACT

The urinary system can be thought of as a series of connected structures that filter, collect, channel, and store urine (155). In each of the body's two kidneys, blood is filtered through a multitude of microscopic filtering units. The resulting urine, containing soluble body wastes and electrolytes that must be discarded to keep the body's fluids in balance, drains into the hollow core of each kidney by way of the renal calices. These calices, finger-like protrusions that extend up into the solid substance of the kidney, collect the urine and channel it into the core, the renal pelvis. From each renal pelvis, urine then passes through one of the two respective tube-like ureters to the urinary bladder. There it is collected and stored until urination occurs and the urine passes through the urethra out of the body. Figure 1 diagrams the structure of the urinary tract.

Stones tend to be located at specific sites in the urinary tract. A renal calix, where the urine first filters into the kidney's core, is a natural alcove where stones may lodge and grow. Because there are numerous calices, a single calix stone may not

Figure 1.—Diagram of the Urinary Tract



NOTE: Figure is not drawn to scale.

SOURCE: Adapted from Blue Cross and Blue Shield Association, "Extracorporeal Shock Wave Lithotripsy: Clinical Assessment, Utilization, and Cost Projections," Chicago, IL, May 1985.

obstruct urine flow or lead to any other symptoms of stones. Larger stones may form in the renal pelvis itself. If these grow to mold themselves to the inner contours of the pelvis and calices, they are called "staghorn" because of their obvious and dramatic appearance on an X-ray. Large staghorn stones are potentially life threatening, and they can also be quite difficult to remove.

Stones are frequently found at the junction of the renal pelvis and the ureter or at a position approximately one-third down the ureter, where the ureter's diameter tapers slightly as it crosses blood vessels. Migrating stones may lodge at these points, blocking urine flow and necessitating removal. Finally, stones can be found at the junction of the ureter and the bladder or in the bladder itself. Lower urinary stones—those occurring in the urethra, bladder, or lower portions of the ureters—are relatively uncommon in the United States.

The causes of urinary stones have been vigorously discussed for some time and are still the subject of intensive research. Among the credible theories are that stones are the result of supersaturation and crystallization of mineral substances in the urine; that there exists a natural stone inhibitor in urine that is absent in some people; and that abnormal macromolecules or crystalline structures may induce stone formation. A combination of these theories probably is the best explanation for the cause of upper urinary tract stones (20,33,44,138,198). And, although in some cases urinary stones can be attributed to a specific disease or a metabolic abnormality,[1] in most cases the factors leading to the onset of stone disease are obscure (198).

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[1] Primary hyperparathyroidism, renal tubular acidosis, cystinuria, primary hyperoxaluria, recurrent infections, and sarcoidosis all play a role in stone formation (33).

EPIDEMIOLOGY OF UPPER URINARY STONES

There are four main types of upper urinary stones, which are summarized in table 1 according to their relative frequencies in the stone-forming population and their densities as they appear radiographically (on X-rays). Calcium-based stones are by far the most common in the United States and are generally subcategorized according to their secondary components. They are also the least well understood in their etiology. Struvite stones, composed of magnesium ammonium phosphate crystals, are also fairly common and are associated with urinary tract infections. The least common stones are those composed of cystine (a sulphur-containing amino acid) or uric acid. Cystine stones are associated with an inherited disease that results in elevated excretion of this and other amino acids. Uric acid stones occur in persons with elevated levels of uric acid in the blood (such as persons with gout) or urine and in persons with low urinary pH (52,198).

Table 1.—Relative Frequencies and Radiodensities of Major Types of Urinary Stones

Stone type	Relative frequency among stones	Radiodensity[a]
Calcium stones	70-80%	most dense
Calcium phosphate	5-10	
Calcium oxalate/phosphate	30-45	
Calcium oxalate	20-30	
Struvite	15-20	
Cystine	3- 3	least dense
Uric acid	5-10	radiolucent

[a]The radiodensity of a stone indicates the ease with which it can be visualized on X-ray.

SOURCE: K.N. Van Arsdalen, "Pathogenesis of Renal Calculi," *Urologic Radiology* 6:65-73, spring/fall 1984.

Incidence of Urinary Stones

Data on the incidence[2] of urinary tract stone disease in the United States come from three sources: targeted surveys of hospitals, hospital discharge abstract data collected by the National Center for Health Statistics (NCHS) and the Commission on Professional and Hospital Activities (CPHA), and studies of urinary stones in specific populations. The estimates of stone incidence discussed in this section are summarized in table 2. As this table shows, the estimates vary considerably and do not lend themselves to simple interpretations.

The first estimate of urinary tract stone incidence was obtained from a survey of U.S. hospitals in 1952 (16). A discharge diagnosis of urinary tract stones was used to define a case, and incidence was estimated at 0.95 per 1,000 persons for that year. Another questionnaire survey, conducted in 1975, yielded an estimated incidence of 1.64 per 1,000 persons for 1974 (157). Although these figures suggest a 73-percent increase in perceived incidence over the 22-year period, they are of questionable accuracy because the two studies were greatly hampered by low response rates, which may introduce biases. (The response rates for the 1952 and 1975 surveys were 11 and 27.2 percent, respectively.) More recent data from NCHS, collected through the annual National Hospital Discharge Survey, indicate that the incidence of a primary hospital discharge diagnosis of upper urinary tract stones in the United States was 1.29 per 1,000 persons in 1982 and 1.42 per 1,000 persons for 1983 (195,196). Data from CPHA have produced similar estimates of incidence with considerable geographic variation (37).

A limitation of all of these estimates of the incidence of urinary stone disease in the United

Table 2.—Summary of Estimates of the Incidence of Urinary Stones in the United States

Source	Year	Urinary stones per 1,000 population	Population studied
Johnson, et al., 1979	1950	0.57[a]	Rochester, MN, residents
Boyce, et al., 1956	1952	0.95	U.S. inpatients
Hiatt, et al., 1982	1970-72	1.22	San Francisco area inpatients
Sierakowski, et al., 1978	1974	1.64	U.S. inpatients
Johnson, et al., 1979	1974	0.80[a]	Rochester, MN, residents
Hiatt, et al., 1982	1971-75	0.36	Northern California ambulatory patients
National Center for Health Statistics	1982	1.29	U.S. inpatients
National Center for Health Statistics	1983	1.42	U.S. inpatients
Commission on Professional and Hospital Activities	1983	1.42	U.S. inpatients

[a]Figures given here are implied. Reported figures are 0.79 (males) and 0.36 (females) for 1950 and 1.24 (males) and 0.36 (females) for 1974.

SOURCES: W.H. Boyce, F.K. Garvey, and H.E. Strawcutter, "Incidence of Urinary Calculi Among Patients in General Hospitals, 1948 to 1952," *J. Am. Med. Assoc.* 161:1437-1442, 1956; R.A. Hiatt, L.G. Dales, G.D. Friedman, et al., "Frequency of Urolithiasis in a Prepaid Medical Care Program," *Am. J. Epidemiology* 115(2):255-265, 1982; C.M. Johnson, D.M. Wilson, W.M. O'Fallon, et al., "Renal Stone Epidemiology: A 25-Year Study in Rochester, Minnesota," *Kidney International* 16:624-631, 1979; R. Sierakowski, B. Finlayson, R.R. Landes, et al., "The Frequency of Urolithiasis in Hospital Discharge Diagnoses in the United States," *Investigative Urology* 15:438-441, 1978; U.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, "Number of Inpatients Discharged from Short-Stay Hospitals, by Category of First Listed Diagnoses, United States, 1982 (table 4), in National Center for Health Statistics—1982 Summary: National Hospital Discharge Survey, No. 95, Dec. 27, 1983; U.S. Department of Health and Human Services, Public Health Service, National Center for Health Statistics, "Detailed Diagnoses and Surgical Procedures for Patients Discharged from Short-Stay Hospitals, United States, 1983," *Vital and Health Statistics* 13, No. 82, DHHS Pub. No. (PHS)85-1743, Hyattsville, MD, March 1985; Commission on Professional and Hospital Activities data, as cited in H. Alder, *Lithotripters: Noninvasive Devices for the Treatment of Kidney Stones* (Chicago, IL: American Hospital Association, 1983).

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[2] "Incidence" is defined as the number of newly diagnosed cases in the general population over a specified time period. It is distinct from "prevalence," which refers to the total number of cases existing in the population during a specified time.

States is their reliance on hospital discharge data. Counting discharges overestimates the incidence of "hospitalizable" stone disease because of possible multiple admissions for the same stone. Furthermore, in the case of the NCHS estimates, the data include only discharges for which urinary stones were the primary diagnosis. Including discharges with a secondary diagnosis of stones increases the estimates by about one-third (3). On the other hand, as demonstrated by one of the following studies, a large proportion of stones—perhaps a majority—do not require hospitalization. Thus, on balance, these hospital studies probably underestimate the true incidence of stone disease. Still, they do indicate a trend towards an increase in incidence of urinary stones in the United States over time.

One of the best available estimates of the incidence of urinary tract stones comes from a 25-year study of Rochester, Minnesota residents, which showed an increase in the annual age-adjusted incidence of urinary tract stones from 0.79 per 1,000 men in 1950 to 1.24 per 1,000 men in 1974 (83). The incidence in women remained stable for this period at 0.36 per 1,000. These data represent as close to a complete sample as feasible and include diagnoses made in ambulatory as well as in hospitalized patients. The 57-percent increase in incidence rates of urinary tract stones in men supports the observed trend from the hospital surveys.

The most recent study on the epidemiology of urinary tract stones was reported from the Kaiser Foundation Health Plan in northern California. First, ambulatory clinic diagnostic information from the San Francisco Medical Center was examined for "new or recurrent" stones covering the period 1970 to 1972. The results showed an age-adjusted annual incidence rate of 1.22 per 1,000 members—1.81 per 1,000 men and 0.59 per 1,000 women (75). A second calculated incidence rate was based on hospital discharge diagnoses for the entire Northern California Kaiser Foundation Health Plan from 1971 to 1975. Based on the hospital data, the age-adjusted annual rate for urinary tract stones was calculated at 0.36 per 1,000 members—0.52 per 1,000 men and 0.19 per 1,000 women (75). Although the geographic populations compared in this study are by no means identical, the results suggest that estimates of incidence based solely on hospital discharge data may underestimate the total incidence of diagnosed urinary stones by a considerable amount.

Distribution of Stones

It has long been noted that urinary stones are more common in some populations than in others. Some of the predisposing factors to stone formation, such as certain diseases that lead to metabolic disorders, clearly have genetic components (33). Racial, ethnic, and familial tendencies toward stone formation have also been postulated more generally; for example, in the United States, Caucasians have a higher recognized incidence of urinary stones than Native Americans or persons of African or Asian ancestry (44,75,165). However, it is often difficult to separate hereditary factors from dietary and other lifestyle differences.

Distribution of urinary stones in the population varies considerably according to age and sex. The Rochester and Kaiser studies found consistently higher stone incidence in men than in women (75,83). NCHS data confirm this tendency for the United States as a whole (195), but as a generalization it requires two important qualifications. First, it may not be true for some subpopulations; black men and women appear to have approximately equal probabilities of developing stones (165). Second, the incidence of stones at autopsy is also approximately equal for men and women in the United States. This fact implies that much of the higher incidence in men is due to earlier onset and recurrence of stones (44).

The lifetime incidence of urinary tract stone disease also varies by sex, ethnicity, and socioeconomic factors, but researchers have estimated it at approximately 10 percent for American men (16,83,157). Stones peak in incidence in men between 40 and 60 years of age, and a stable rate persists through the seventh decade (83). A decline in incidence in men and women older than 70 years of age was observed in both the Rochester and Kaiser studies (75,83). The incidence of urinary tract stones in persons older than 65 years of age is therefore similar to the average incidence in the general population.

The Southern United States is frequently referred to as the "stone belt," and with good cause. The incidence of upper urinary stones there in 1983, as measured by hospital primary discharge diagnosis, was 1.84 per 1,000 population, compared to 1.39 in the Midwest, 1.16 in the Northeast, and 1.00 in the Western United States (37). Differences in diet and climate have been cited as possible reasons for these disparities (44), but it is possible that physician and hospital practice patterns also play a role in the apparent regional differences in stone incidence (3).

Because a high incidence of upper urinary stones seems to be influenced by diet and by the industrial development of an area, it has been associated with affluence. However, the Kaiser study found an inverse correlation between a history of urinary tract stones and the educational background of the person (75).

Stone Recurrence

A majority of patients who have had one upper urinary stone develop another one (83). More precise estimates of stone recurrence are available, but they tend to be difficult to compare because they use different followup periods and other measurements. Comparability is also hampered by possible confounding factors, such as distributional factors (e.g., geography) and diet and treatment regimens.

One retrospective evaluation of 538 patients with upper urinary tract stone disease for a minimum of 10 years reported that 75 percent had recurrences over a mean period of 18.5 years (206). In another study, researchers followed 416 patients at a London stone clinic for a mean period of 7.6 years and reported that 36.1 percent of the sample developed a second stone (99). The Rochester study sample had a symptomatic recurrence rate of 30 percent for women and 45 percent for men over 14 years of followup, with the highest recurrence in the first year (83). Other investigators have reported an overall average interval between first and second stones of 4.5 years, and they believe that natural recurrences approach 100 percent if patients are followed for a long enough time (33).

Second stones can often be prevented with medical treatment, even when the exact cause of the metabolic disorder leading to the stone is obscure. For example, the factors stimulating the body to create an environment leading to calcium stones are largely unknown. However, metabolic evaluations of people with calcium stones show that up to 60 percent have high concentrations of calcium and/or uric acid in the urine (33). The presence of high uric acid concentrations alone appears to predict a more severe course of stone formation, with comparatively shorter inter-event intervals, than when high concentrations of both are present (34). Medical treatment of the metabolic abnormalities in calcium stone formers decreases the recurrence rate in patients with frequent episodes (32,50,118,130).

UPPER URINARY STONES AND TREATMENT TECHNOLOGIES

The above discussion suggests that upper urinary tract stones in the United States are common, have increased in incidence over the past 30 years, vary in distribution across regions and populations, and primarily affect men during the economically productive period of their lives. Although persons at risk of stone formation can be identified in a few cases before they develop their first stone and stone recurrence can often be controlled or prevented, a large number of people develop upper urinary stones for reasons still unclear to modern medicine.

Of all the factors discussed, one of the most important considerations for treatment technologies remains difficult to quantify: the precise number of stones to be treated. Most current estimates of the number of stones requiring treatment are based on 1983 hospital survey data from NCHS. Used alone, this incidence of 1.42 kidney and ureteral stones per 1,000 population (196) implies the existence of over 336,000 stones per year that lead to hospitalization.[3] This number includes readmissions for the same stone but does not include patients in Federal hospitals, such as Veterans Administration and military hospitals, that are not included in the NCHS survey. Increasing this figure by 30 percent to include all patients with a secondary hospital diagnosis of kidney or ureteral stones (3) yields an estimated 437,000 patients hospitalized with stones. If, furthermore, 50 percent of all patients with stones are treated solely in ambulatory settings, as many as 874,000 persons each year may be diagnosed with stones.

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[3] This figure assumes a U.S. population of 237 million (184).

Not all of the patients hospitalized with stones undergo aggressive treatment; in 1983, approximately 65,000 patients in non-Federal hospitals underwent surgery of the kidney or ureter (155) and approximately 120,000 underwent either surgical or transurethral procedures on the urinary tract (3). A substantial but unknown number of these procedures were for stone removal. Thus, the annual number of patients treated for newly diagnosed kidney or ureteral stones may be as high as 874,000; the annual number having open surgery or its equivalent as treatment for stones may be as low as some proportion of 65,000. The number for whom ESWL is appropriate has been independently estimated by at least four different groups (3,11,14,155) and lies somewhere in this range. That unknown number affects both the use and the costs of ESWL and is itself affected by alternative technologies, patient preferences, physician decisions, and the availability of the technology. These subjects are the topics of the subsequent chapters in this case study.

Chapter 3

Alternative Treatments for Urinary Stones

Chapter 3

Alternative Treatments for Urinary Stones[1]

INTRODUCTION

The past decade has seen a great expansion in the physician's armamentarium of tools to treat and prevent urinary stones. Medical management of stone-forming patients has become more sophisticated and effective, and the diffusion of less invasive surgical procedures and safe, effective stone fragmentation tools has provided physicians with a wide array of choices with which to treat patients. Although the introduction of the Dornier lithotripter on the U.S. market in 1984 has attracted the most attention, in fact there are a number of alternative techniques, both complementary and substitutive, to treat patients with urinary stones.

This first part of this chapter reviews the most widely recognized approaches to treatment, other than extracorporeal shock wave lithotripsy (ESWL), currently available: medical management, including dietary regimens and drug treatment to prevent recurring stones; traditional open surgery to remove stones; transurethral removal of stones; and percutaneous stone removal, a less traumatic surgical procedure to remove upper urinary stones that is gaining increasing acceptance. Because ESWL is discussed in great detail in the next chapter, it will not be included here. The second part of this chapter describes the tools that are used in transurethral and percutaneous procedures to remove, fragment, and dissolve stones. Both the treatment techniques and the instruments employed in them are areas undergoing rapid technological change.

APPROACHES TO STONE TREATMENT

Dietary and Medical Management

Most patients with symptomatic urinary stones initially consult their physicians because of pain (colic) or blood in the urine (hematuria). The majority of these stones are sufficiently small to pass spontaneously, although frequently painfully. Thus, analgesics to relieve pain are a fundamental tool in the management of urinary stone disease (44). Although smooth muscle relaxants have been used to relieve spasm and to promote passage of the stone (121), they are of doubtful value (112). In addition to treatment for pain, acute medical management of stones usually includes a high fluid intake to increase urine flow and encourage the stone to pass.

The size and location of a stone at the time of clinical presentation help to predict its often erratic behavior. Large stones found in the upper urinary tract at the time of diagnosis are the least likely to pass spontaneously and involve the greatest risk of serious complications. In one series of 292 cases, 91 percent of stones 5 mm or smaller passed spontaneously or with the help of endoscopic procedures (described below), but 60 percent of larger stones required surgery (55). Results from other studies have indicated that stones over 7 mm in size impacted in the upper ureter rarely pass spontaneously (146). Stones that have not passed and have remained symptomatic after 6 weeks of conservative therapy are generally considered for removal. Evidence of infection above the stone, refractory pain, ureteral obstruction, and anuria (lack of urine flow) are considered absolute indications for stone removal (112).

Effective long-term medical management is an important preventive measure for any patient who has had a urinary stone. The most basic preventive management includes a prescription to increase fluid intake; in many cases a dietary regi-

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[1] This chapter draws extensively from J.A. Showstack, E.J. Perez-Stable, and E. Sawitz, "Extracorporeal Shock Wave Lithotripsy: Clinical Application and Medicare Physician Payment," paper prepared for Office of Technology Assessment, Washington, DC, Aug. 1, 1985.

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men and/or drug therapy are also prescribed. It has been suggested that dietary management is often overlooked or underappreciated (163), perhaps because patient compliance can be difficult. Appropriate diet and medication therapy requires that the patient be evaluated thoroughly to identify metabolic abnormalities, because preventive treatment depends on the underlying metabolic disorder.

For calcium stones, research suggests that a fluid intake that guarantees a minimum urine output of 2 liters per day can decrease recurrence rates in up to 60 percent of patients (77). A moderate calcium restriction of 400 to 600 mg per day may be useful in patients with absorptive hypercalciuria, while other patients with idiopathic calcium stones (those of unknown origin) should avoid an excess of 1 gram of calcium intake per day (119). Dietary restrictions of oxalate, animal proteins, and sodium are occasionally prescribed for patients who have had calcium stones. Table 3 gives some examples of foods high in calcium and oxalate.

A number of drugs to prevent certain types of stones exist and are often useful components of medical management. Evaluations of calcium stone formers can identify the presence of metabolic risk factors, such as excess calcium and/or uric acid in the urine, in about 60 percent (33). Treatment of these patients with one or more of the available drugs has been shown to significantly alter the natural history of recurrent stone formers (32,50,118); some researchers believe they can prevent recurring calcium stones in 97 percent of their patients (130).

Table 3.—Foods Containing High Levels of Calcium or Oxalate

High calcium	High oxalate
Milk	Beetroot
Cheese	Spinach
Ice cream	Rhubarb
Yogurt	Parsley
Foods containing flour	Runner beans
All beans (except green beans)	Chocolate, cocoa, instant coffee, Ovaltine, tea
Lentils	
Fish with bones, e.g., sardines, kippers, herring, salmon	
Dried fruit, nuts	
Chocolate, cocoa, Ovaltine, Horlicks, Bournvita, milk drinks	
Sauces containing milk	

SOURCE: B.E.C. Nordin, A. Hodgkinson, M. Peacock, et al., "Urinary Tract Calculi," *Nephrology*, J. Hamburger, J. Crosnier, and J. Grünfeld (eds.) (New York: John Wiley & Sons, 1979).

Thiazide diuretics, sodium cellulose phosphate, orthophosphates, potassium citrate, and allopurinol are all medications prescribed to help prevent calcium stone recurrence, although none of these drugs is appropriate for all patients with calcium stones. Thiazides, for example, decrease the urinary excretion of calcium by stimulating its reabsorption in the kidney and are especially useful in patients with excess urinary calcium (104). Sodium cellulose phosphate, a medication only recently approved for marketing by the Food and Drug Administration, prevents calcium oxalate stone formation by acting as an ion exchange resin and reducing dietary calcium absorption. Orthophosphates (preparations of acid, neutral, or alkaline phosphates) have been used for some time and also reduce calcium excretion. Potassium citrate, another new drug, acts by alkalinizing the urine and correcting low levels of urinary citrate, which prevents crystallization of calcium salts. Allopurinol therapy is often used as a preventive therapy for recurrent calcium stone formers with uric acid disorders (162).

It is important to note that there is no universal agreement among physicians regarding the effectiveness of the various drug therapies. Some drugs, such as sodium cellulose phosphate and potassium citrate, have been in general use for only a short time. Others, such as the thiazides, have been in use for some time, but the range over which they are effective is still not unequivocably established (29). Some researchers have suggested that dietary modification may be a favorable alternative to drug therapy in many patients with calcium oxalate stones (199).

Medical management of noncalcium stones is likewise vital to preventing recurring stones. Struvite stones are usually associated with repeated urinary tract infections and frequently recur. Medical therapy to eliminate these stones once they have formed has had some encouraging results, but it has been hampered in wide application by drug side effects and lack of efficacy (207). Prevention of future struvite stones in a patient, however, is usually effective and can be achieved by the administration of acetohydroxamic acid, a bacterial enzyme that helps prevent the formation of struvite stones but has only marginal effects on formed stones (207). Uric acid stones can often be associated with an identifiable metabolic disorder, and in these cases dietary limits on animal protein intake may help prevent stone recurrence. These patients may also be given medications to alkalinize the urine. (An alkaline medication can be as simple as sodium bicarbonate, common baking soda.) Cystine stones result from an inherited renal disorder; as with many uric acid stones, preventive therapy for these stones usually includes administration of an alkaline substance to buffer the acid urine (44).

Open Surgery

Major surgery to remove stones in the kidney (nephrolithotomy) or ureter (ureterolithotomy) has been standard treatment for large or troublesome upper urinary stones for many years. Since surgery for removal of stones, like any other major surgical procedure, carries a significant morbidity, a small risk of death, and an increased risk of kidney damage with subsequent surgeries, it has usually been prescribed only for stones accompanied by intractable pain, severe or recurrent infection, urinary obstruction, or other complications (84). A typical patient undergoing open stone surgery requires a 10-day hospitalization and a convalescence of about 6 weeks (129,170).

Problems such as persistent pain, infection, and obstruction are more common with stones located in the ureter than with stones located in the kidney, and indications for ureter stone removal through surgery are consequently clearer. Ureterolithotomy is successful in removing stones in 99 percent of cases, and failures are usually related to surgical difficulties in locating the ureter or the stone (112). In one series of 445 patients undergoing ureterolithotomy, 18.4 percent had surgical complications, including three deaths (58).

Indications for surgical removal of stones lodged in the kidney are less clear and often depend on the physician's judgment regarding whether the stone is likely to pass spontaneously. Struvite stones associated with recurrent infections are an exception, and surgery has been the standard of care (161). A retrospective review of 951 open surgical procedures for stone removal reported an associated mortality rate of 0.6 percent; serious complications, including hemorrhage in excess of 1 liter, were found in an additional 13 percent of cases (15). Investigators studying a recent series of 100 patients undergoing nephrolithotomy reported that 4 percent had stones left behind (18). Partial nephrectomy (removal of part of the kidney) is necessary to remove some stones

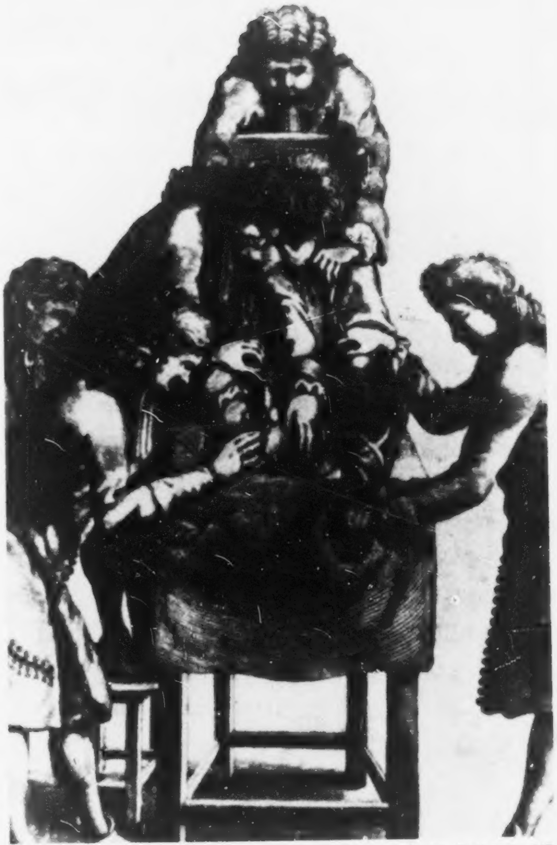

Photo credit: National Institutes of Health, Bethesda, MD

Open surgery for treatment of urinary stones has been performed for centuries. This lithograph shows such an operation performed in 1682.

and is associated with overall morbidity rates as high as 40 percent; mortality in one series of 96 patients was 1.7 percent (35). The risk of losing kidney function increases with successive surgeries.

Traditional open surgery for removal of stones is now on the decline, largely due to the existence of safer, less costly, and less traumatic alternatives that appear to be equally effective in most instances. However, it will continue to be the treatment of choice in a small proportion of cases not suited to other approaches (134).

Transurethral Manipulation[2]

Removal of urinary stones can be attempted "from below," that is, an instrument can be passed up through the urethra and the bladder into the ureter, often making surgery unnecessary. Transurethral procedures are useful primarily for lower urinary stones; use of these procedures for upper stones results in fewer successful removals and a higher complication rate (45). Sometimes tools to extract the stone are not even necessary since mechanical dilation of the ureter may allow passage of the stone; simple catheterization (insertion of a tube) of the ureter, with or without dilatation, induces spontaneous passage of stones in 21 to 37 percent of cases (112). If passage does not occur, the stone may be grasped and removed. Transurethral meatotomy (opening the mouth of the ureter where it enters the bladder) is indicated when the stone or grasping instrument is impacted at the junction of the ureter and the bladder, but this maneuver should not usually be necessary (45).

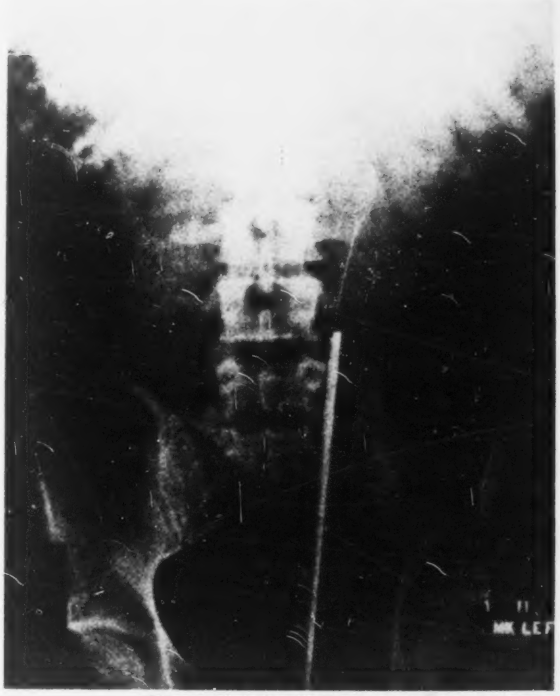

Photo credit: National Institutes of Health, Bethesda, MD

Some urinary stones can be removed endoscopically, with tools passed up the urinary tract. A stone basket, used to trap and extract ureteral stones, can be faintly seen protruding from the end of a ureteroscope in this X-ray.

Stones in the lower third of the ureter may be extracted transurethrally by use of a wire or nylon basket. The success rate of this procedure varies, but it has been reported to be between 69 and 77 percent in two series of 173 and 121 patients, respectively (95,114). A basket extraction technique using a specially designed angioplasty balloon to dilate the ureter had a reported success rate of 95 percent in 39 patients (145). Transurethral removal of stones in the upper portions of the ureter has been attempted using a variety of basketing, grasping, and fragmenting instruments, but the safety and usefulness of this procedure are not yet generally accepted (8,197).

Complications of transurethral extraction techniques include perforation at the junction of the ureter and the bladder, damage to ureteral integrity, stone movement into the kidney, renal colic, bleeding, and infection (43). Evidence of bleeding is present in 10 to 15 percent of cases at the conclusion of the procedure but is usually no longer demonstrable 48 hours later (95). Open surgical procedures are required in 5 to 10 percent of patients after attempted stone removal by transurethral manipulation (95,112,145).

Percutaneous Procedures

Endourologic equipment and techniques developed during the past 15 years allow percutaneous access to stones in the upper urinary tract without resorting to open surgery. In combination with ESWL, these percutaneous or "through the skin" techniques will most likely replace traditional open surgery for most renal and upper ureteral stones. In the most common form of percutaneous procedure, a tube is passed into the renal pelvis through a small incision in the lower back and a variety of techniques may be used to remove the stone.

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[2] For the purposes of this study, "transurethral manipulation" includes procedures that extend up into and through the ureter as well.

Percutaneous nephrostomy (the creation of a passage to the kidney through a small opening in the skin) was first described in 1955 (65), but the technique was not widely applied to the therapy of urinary tract stones until the late 1970s (167). Access to the renal collecting system is achieved by direct puncture under fluoroscopic or ultrasound guidance; a guide wire or catheter is inserted through the needle and advanced down the ureter to maintain the tract (160). The nephrostomy tract is then progressively dilated under local or general anesthesia. The procedure is frequently performed in two stages, particularly for stones larger than 1.5 cm (129) or in cases where bleeding after dilatation obscures visibility. In this two-stage procedure, nephrostomy and dilatation are performed first, and further dilatation and stone extraction are performed at a later time. However, percutaneous nephrostomy has also been accomplished as a one-stage procedure (129).

The development and modification of equipment to dilate the nephrostomy tract rapidly and to destroy stones prior to removal have increased the applicability of percutaneous nephrostomy (155). Average hospital stays of 5 to 8 days have been reported for patients undergoing percutaneous stone removal (17,129,132,151) and may be declining; outpatient percutaneous lithotripsy has recently been reported (128).

The nephrostomy procedure and tract dilatation in order to pass the nephroscope are associated with the majority of significant complications of percutaneous procedures. Stables reviewed the experience of 1,207 patients and reported a 4-percent incidence of significant complications, mostly hemorrhage and infection, and one death (166). In general, most problems with nephrostomy tubes are mechanical, involving displacement or blockage. Failed attempts at placement are rare (142).

The Mayo Clinic, after experience with 1,032 percutaneous manipulations for stone removal, reported a delayed bleeding rate of nearly 1 percent from significant vascular injuries (120). Seven patients were treated successfully with transcatheter embolization techniques, two resolved spontaneously with observation, and one underwent an emergency flank exploration resulting in nephrectomy (120). Other researchers have found that perforations of the renal collecting system usually heal spontaneously after 24 to 48 hours (18). Percutaneous lithotripsy using ultrasound instruments does not appear to negatively affect the function of the operated kidney, at least in the short run (101).

INSTRUMENTS FOR STONE DESTRUCTION AND REMOVAL

Mechanical and Chemical Removal

A variety of mechanical tools is available to crush or extract stones. Loops and wire baskets to ensnare stones are standard supplementary tools for transurethral manipulation of lower ureteral stones, although their usefulness in transurethral manipulation of upper urinary stones is debatable (45). Wire baskets and forceps are useful adjuncts to percutaneous renal stone extraction (97,160), and a "stone punch" to mechanically crush the stone has also been successfully employed in a percutaneous procedure (159). Although "power lithotripsy" to fragment stones for easy passage or removal is becoming common, mechanical removal is likely to remain an option for small stones and large fragments, particularly for lower urinary stones.

Chemolysis, the prolonged application of drugs to a stone to dissolve or reduce it, has not been widely accepted as a therapeutic alternative to surgical or mechanical removal. The long hospital stay (up to 2 months) necessitated by irrigation therapy, which is usually administered through a nephrostomy tract, limits the usefulness of the technique. However, chemolysis does seem to have a role in certain situations. In one series of 150 patients with symptomatic stones treated by percutaneous chemolysis, for example, complete dissolution was achieved in 70 percent and another 15 percent had only tiny fragments remaining (122). Progress was monitored every 3 to 4 days by X-rays, and the total duration of irrigation was 1 to 4 weeks (122).

Struvite, uric acid, and cystine stones are the most amenable to chemolysis (160). Some calcium-containing stones can also be dissolved in this manner, but calcium oxalate and calcium phosphate stones resist dissolution therapy (160). Chemolysis carries with it a substantial risk of infection, and death as a result of complications is not unknown (152). Nonetheless, the procedure seems to have a place in the urologist's armamentarium. Combination therapy with ESWL has been attempted by at least two groups (47,149), and it may be a comfortable niche for future application of chemolysis.

Electrohydraulic Lithotripsy

Electrohydraulic lithotripsy is the oldest form of "power" lithotripsy. The electrohydraulic lithotripter releases high impulse discharges from an electrode at the tip of a flexible probe, which is placed next to the stone. The shock waves generated by these discharges are of sufficient force to disrupt the hardest stone. Electrohydraulic lithotripsy has been used with both transurethral and percutaneous endoscopic techniques.

Transurethral electrohydraulic lithotripsy is a highly effective means of bladder stone removal and has become an accepted practice for this use (108). Application of electrohydraulic lithotripsy to percutaneous techniques has been limited to small series (30,63), and there is far less reported experience than for ultrasonic lithotripsy (see below). The electrohydraulic lithotripsy probe must not be used 5 mm or closer to soft tissue or severe damage will result, making it inappropriate in most cases for ureteral stones (106). However, it may be useful for fragmenting stones in the renal pelvis and calices. A British group has reported the safe removal of such stones in 17 patients without a single perforation, and they believe that electrohydraulic lithotripsy is superior to ultrasonic lithotripsy for all but very soft stones (107).

Ultrasonic Lithotripsy

Percutaneous ultrasonic lithotripsy was first performed in 1977 (87), but clinical experience has expanded greatly since that time (13,17,18,30,151), and the safety and usefulness of the technique are widely accepted (8). The ultrasound probe emits high-frequency ultrasonic energy that has a simple drilling effect upon direct exposure to the stone (155). Direct contact of the probe tip and stone is essential for effectiveness of ultrasonic lithotripsy. A suction channel is attached to the hollow probe in order to continuously remove stone fragments, an advantage of ultrasonic over electrohydraulic lithotripsy (97). Transurethral application of ultrasonic lithotripsy to bladder stones is considered effective (79), and experience with stones in the ureter and renal pelvis is expanding rapidly.

As with many technologies, use of ultrasonic lithotripsy as the stone removal technique in percutaneous procedures demonstrates a "learning

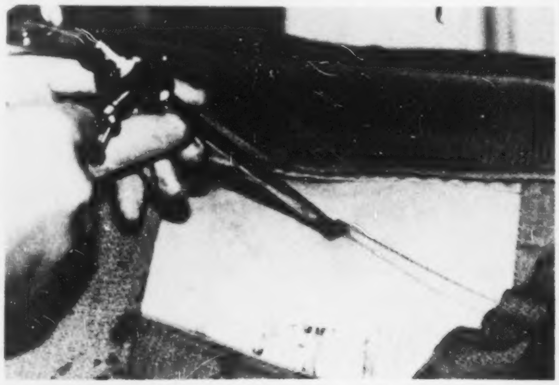

Photo credit: National Institutes of Health, Bethesda, MD

Kidney stones can be fragmented and removed through a percutaneous tract using ultrasonic or electrohydraulic probes, requiring only a small incision.

curve" effect for both efficacy in removing stones and reduction of serious complications (150,204). A number of groups have reported considerable experience with this method. Segura and colleagues successfully removed 96 percent of 148 kidney stones and 86 percent of 50 ureteral stones by percutaneous ultrasonic lithotripsy (151). Major complications were encountered in 3.2 percent of this series, including two patients who required open surgery (151). Brannon and colleagues have reported their 2-year experience with 250 consecutive patients, in which targeted stones were removed in 97 percent of patients by percutaneous ultrasonic lithotripsy (18). A repeat nephrostomy was performed in 20 patients (8 percent), and 32 patients (13 percent) required an additional procedure (e.g., transurethral manipulation) to remove the stone. The overall complication rate was 6.8 percent, but significant delayed bleeding occurred in eight patients (3.2 percent), and three of these required angiographic embolization to control hemorrhaging (18).

A community hospital urology group has reported an 87 percent success rate in removing stones from 38 patients by percutaneous ultrasonic lithotripsy, with an overall complication rate of 7.8 percent (13).

Experimental Endoscopic Lithotripsy Instruments

Laser lithotripters and and microexplosion techniques are being investigated as potential methods to fragment stones endoscopically, but both are currently still in the early experimental stages. Lasers are being investigated as a power source to fragment stones extracorporeally as well as endoscopically, but neither method has yet undergone clinical trials (11,201,202). Microexplosion lithotripsy, based on a small controlled explosion incorporated into a catheter that creates shock waves, is also being investigated as a possible method of fragmenting urinary stones. It has been used on a small number of patients in Japan with bladder stones, with some success. The small number of bladder stones in developed countries makes ureteral and renal stones the more widespread goal of this therapy, but these uses are still highly experimental (200).

Chapter 4

ESWL: Efficacy, Safety, and Regulation by the Food and Drug Administration

Chapter 4

ESWL: Efficacy, Safety, and Regulation by the Food and Drug Administration

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INTRODUCTION

Extracorporeal shock wave lithotripsy (ESWL) is a novel approach to stone treatment; it has existed only since the beginning of the 1980s and is unlike any of the other alternatives in either cost or character. Currently approved for use only for stones in the kidney and upper ureter, it has the potential to be extended to treatment of lower urinary stones, gallstones, and, possibly, a diverse range of other medical problems. Only one manufacturer, Dornier Medical Systems of West Germany, presently has approval to market an ESWL device in the United States. However, at least three American firms, as well as manufacturers in other countries, are working on their own extracorporeal lithotripters.

This chapter first describes the Dornier lithotripter and its early development in West Germany. It then discusses the investigational period of the device in the United States that culminated in the Food and Drug Administration's (FDA) premarket approval of the device in December 1984. The next section of this chapter summarizes the current status of ESWL and the evidence on its safety and efficacy. The final section concludes with a brief discussion of other ESWL devices currently under development in the United States and potential future applications of ESWL.

DESCRIPTION OF THE DORNIER LITHOTRIPTER

In the Dornier lithotripter, shock waves are generated outside of the body and transmitted through water and the outer tissues of the body to the stone in the kidney or upper ureter. Immersion of the patient in a water bath allows the shock wave to pass from the generator (an electrode) to the patient without either damaging tissue or damping the wave, since water and tissue have similar acoustic impedance properties. The water's temperature, gas content, and conductivity are controlled by a treatment system in the lithotripter (187).

The shock waves are generated by an underwater spark from an electrode located at the first geometric focus of a semi-ellipsoidal reflector. The stone is positioned at the second focus of the reflector, which is the point of highest energy density. A two-dimensional radiographic scanning system, using two X-ray units, and a patient-positioning system ensure proper location of the stone. The force generated by the shock wave is concentrated on a spherical area 2 cm in diameter (the second focus). A large pressure zone is created as the shock wave passes from tissue or urine into the stone. This pressure exceeds the strength of the stone material and causes its destruction. Repeated shock wave applications result in the fragmentation of a stone into small pieces (2 mm or less), which normally are passed spontaneously out of the body in the urine (187).

Each ESWL treatment may use from less than 1,000 to more than 2,500 shocks. The shocks are synchronized with the patient's heart rhythm, as monitored by an electrocardiogram, and are delivered during the contraction of the heart, when it is not responsive to electrical stimuli. This arrangement avoids the complications, experienced in the early clinical trials, of triggering arrhythmias of the heart (22). Appendix C describes the properties of shock waves and the design of the Dornier lithotripter in more detail.

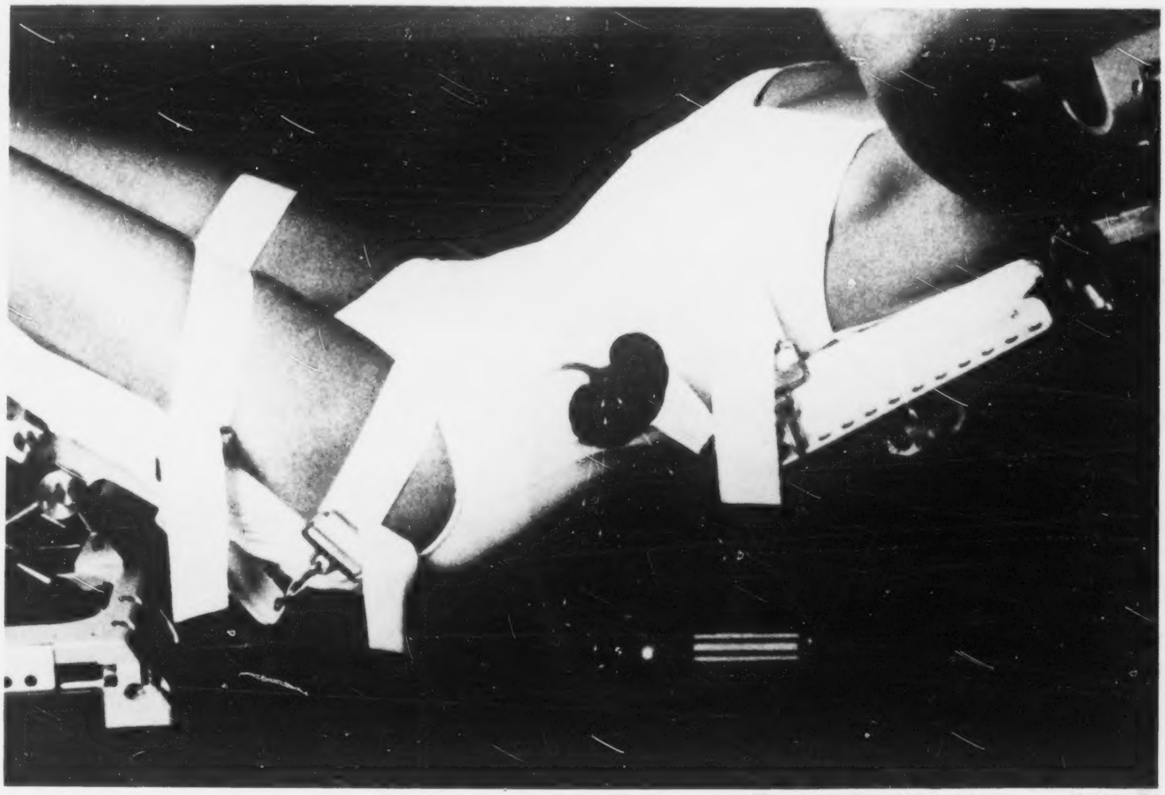

Photo credit: Dornier Medical Systems, Inc., Marietta, GA

In the Dornier lithotripter, shock waves produced by a spark-gap electrode travel through a water bath and the body of the patient to the point of the urinary stone.

EARLY STUDIES OF ESWL[1]

Shock waves are phenomena closely identified with studies of explosions and of aerospace; the force created by a jet breaking the sound barrier, for example, is a shock wave. Accordingly, a West German aerospace firm (Dornier) was the first to successfully apply extracorporeal shock wave technology to treatment of urinary stones.

The fundamental problem to overcome in early studies of ESWL was focusing the wave on the stone without causing other tissue damage or lessening the power of the wave to the point where it was not effective (22). Initial *in vitro* studies of stone fragmentation were performed on stones freely suspended in a water-filled plastic bag. Studies in rats showed that shock waves caused destruction of lung tissues, but no trauma to other biological tissues. Studies in larger animals supported the finding that the kidney itself was not harmed by the shock waves, but they also were not successful in every case at fragmenting the stones into pieces that could be spontaneously discharged. The animal trials did result in a rejection of ultrasound in favor of X-rays as a reliable method of imaging the precise location of the stone (22).

The first description of clinical experience with ESWL was published in 1980. In a series of 23 pa-

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[1] This section and the one following draw extensively from J.A. Showstack, E.J. Perez-Stable, and E. Sawitz, "Extracorporeal Shock Wave Lithotripsy: Clinical Application and Medicare Physician Payment," paper prepared for the Office of Technology Assessment, Washington, DC, Aug. 1, 1985.

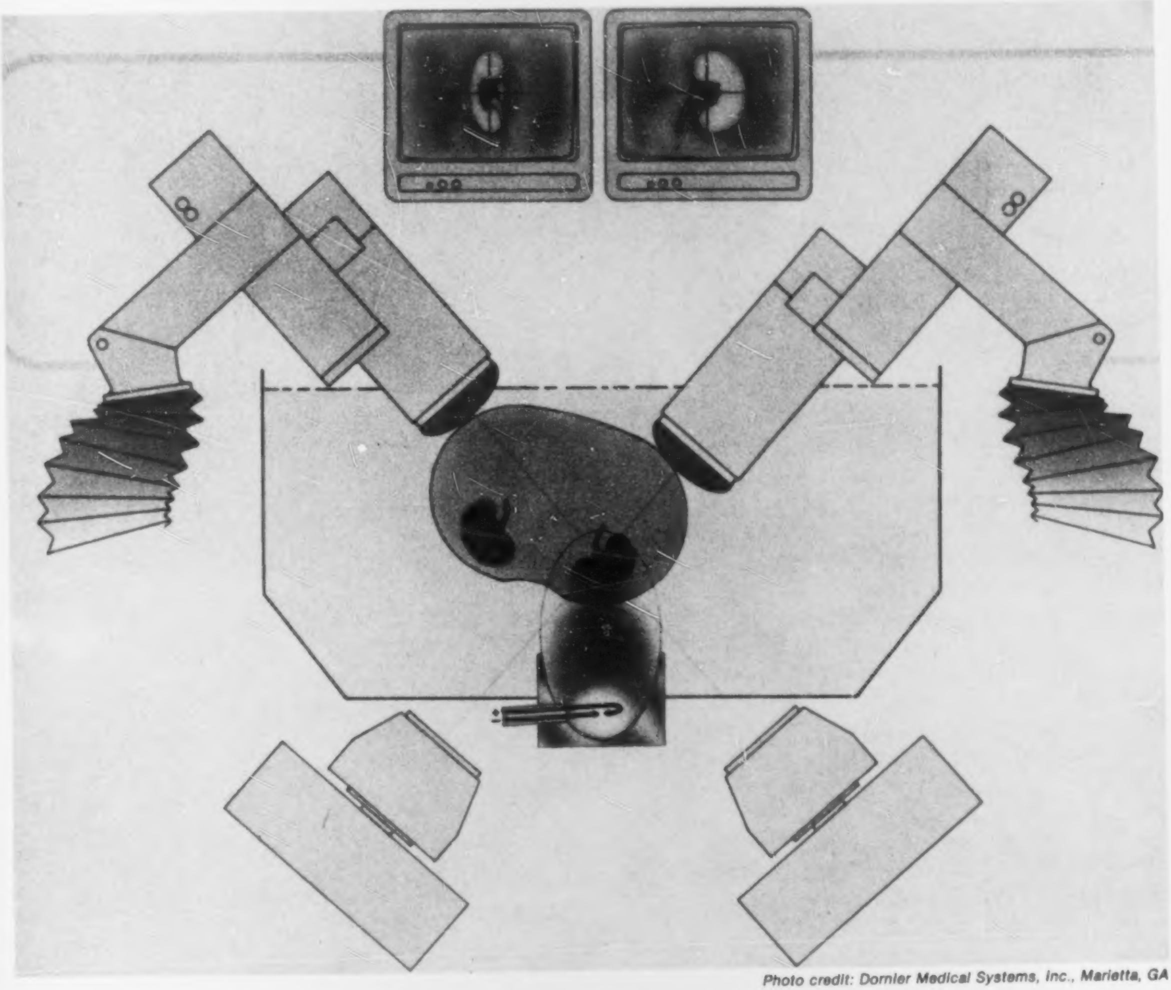

Photo credit: Dornier Medical Systems, Inc., Marietta, GA

The location of the stone in the Dornier lithotripter is defined in two dimensions by X-ray devices that are attached to the lithotripter.

tients with upper urinary stones treated with ESWL, 20 patients had stones that were successfully destroyed by ESWL and expelled spontaneously. Only two of these patients were reported as having renal colic after the procedure, but hematuria was present in all (23). The three failures in this series (two patients with ureteral stones and one with a staghorn stone) all required subsequent open surgical procedures (23). Although general anesthesia was used in 65 percent of the patients in this series, eight of the last nine patients undergoing ESWL were given only epidural (regional) anesthesia.

Updates on clinical experience with ESWL were published in 1982 and 1983, demonstrating very positive results with renal stones but less success with ureteral stones (25,26). Not all patients with renal stones were selected for ESWL. The initial exclusion criteria in selecting patients were: 1) obstruction of the urinary tract, 2) infection of the urinary tract, 3) stones larger than a cherry, 4) insufficient contrast density for precise localizations (the stone could not be seen clearly enough on X-ray to position the patient precisely), and 5) existence of other significant medical problems (22). Thirty-nine percent of the first 206 patients treated with ESWL had previous surgery on the treated kidney for stone disease (25).

A third update in 1983 reported on 498 patients (24). A 3-month post-ESWL evaluation showed 90 percent free of stones, 9 percent with residual stones of small size, and only 1 percent (four patients) requiring open surgical procedures (24). The composition of stones treated with ESWL was reported as 80 percent calcium containing, 15 percent struvite, and 5 percent uric acid or cystine, approximately the same as the distribution of stone types in the population. In mentioning successful subsequent treatment of 30 patients with ureteral stones, the investigators emphasized that all of these stones had moved into the ureter 6 weeks or less before ESWL treatment (24).

In 1984, Chaussy and colleagues summarized the Munich experience with 945 patients undergoing 1,068 ESWL treatments (27). Three months after ESWL, 89.5 percent of patients were free of stones, 10 percent had detectable stones on radiographic evaluation, and 0.6 percent had undergone open surgery. To achieve this efficacy rate, adjuvant procedures were necessary in 76 patients (8 percent); transureteral manipulations were conducted in 33 (3 percent), and percutaneous nephrostomy was necessary in 43 (5 percent) (27). One ESWL treatment was sufficient in 87 percent, but 11 percent and 2 percent of patients underwent two and three treatments, respectively (27).

Although the high proportion of treated patients with previous surgery on the affected side indicates a patient population of recurrent stone formers with severe symptoms, information is lacking on patient selection and severity of symptoms before ESWL treatment. The early exclusion criteria were eventually discarded, and the only remaining contraindication noted in the 1984 update was "pathologic drainage conditions" below the stone and location inferior to the iliac crest (in the lower part of the ureter, where visualization of the stone is difficult because of the intervening pelvic bone) (27). More than 100 ureteral stones were treated successfully with ESWL when their presence in the ureter did not exceed 6 weeks (27).

REGULATION BY FDA AND CLINICAL TRIALS IN THE UNITED STATES

FDA regulates the introduction of drugs, medical devices, and biological products onto the market in the United States. Whenever a manufacturer wishes to market a new medical device, or an old device with new features or uses "that could significantly affect the safety of effectiveness of the device" (21 CFR 807), the manufacturer is required by section 510(k) of the 1976 Medical Device Amendments to notify FDA. If the device is found by FDA to be "substantially equivalent" to a preenactment device, it may be marketed. If not, it automatically becomes a class III[2] device and requires premarket approval before it can be marketed. To receive premarket approval for a device, the manufacturer must submit an application to FDA showing the results of clinical trials and other safety and efficacy information (179).

In order to conduct a clinical trial (using human subjects) in the United States with a device that has not been approved for marketing and that poses a "significant risk" to users, the manufacturer must obtain an investigational device exemption (IDE) from FDA (85). In principle, the manufacturer must not make a profit by selling the device until the device has premarket approval, although this rule is difficult to enforce. When sufficient data have been collected, the manufacturer submits a premarket approval application that includes the evidence of its safety and efficacy and labeling information for the device. Once FDA finds both the evidence and the labeling to be acceptable, it gives the manufacturer approval to market the device (179).

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[2] The 1976 legislation established three classes of medical devices; class III contains those devices for which general controls are insufficient to ensure safety and efficacy, information does not exist to establish a performance standard, and there is a potential for harm (179).

The Dornier company, which had been conducting clinical trials of ESWL in West Germany since 1980, submitted an IDE request to conduct trials in the United States in September 1982 (42). The IDE was granted by FDA in April 1983, and clinical investigations commenced at the Methodist Hospital in Indianapolis, Indiana, in February 1984 (203). The investigations were extended shortly thereafter to five more U.S. hospitals: Massachusetts General Hospital in Boston, Baylor University College of Medicine-Methodist Hospital in Houston, New York Hospital-Cornell Medical Center in New York, University of Virginia Medical Center at Charlottesville, and University of Florida-Shands Teaching Hospital in Gainesville (3). Though FDA did not require that U.S. data be presented in Dornier's premarket approval application, the U.S. trials served the dual purpose of supplementing the German data in the premarket approval application and of allowing the U.S. medical community to become familiar with the device.

The research protocol under the IDE called for each hospital to treat two successive categories of patients. Patients in the first category were required to have the following characteristics:

- a single stone, located in the renal pelvis or calices, that showed up as densely opaque under X-rays and measured less than 2 cm in its longest axis,
- urine that could be sterilized with antimicrobial agents before treatment,
- no obstruction in the urinary tract below the position of the stone,
- normal body structure with no more than 30 percent excess body fat,
- no major coexisting diseases, and
- no significant calicification of the aorta or renal artery.

Once an investigational site had treated 50 such patients, the IDE protocol allowed the treatment of patients with more complicated symptoms, including:

- multiple renal stones,
- stones larger than 2 cm in axial length,
- upper ureteral stones, and
- radiolucent stones (less easily visualized with X-rays) (42,187).

The Gastroenterology-Urology Devices Panel, an advisory panel to FDA, met on May 31, 1984, to consider evidence thus far on the Dornier lithotripter (187). At that time, 317 patients in three U.S. hospitals had been treated with ESWL. Of these, 32 (10 percent) had required two ESWL treatments and 3 (1 percent) had required three treatments. Three patients had experienced minor complications (pancreatitis and urosepsis) associated with the treatment, but all recovered uneventfully in a few days. There were no deaths. The panel, after considering the German data and these corroborative reports, recommended approval of the device subject to minor technical adjustments, labeling requirements, and the submission of followup clinical investigation data and a postmarketing surveillance plan (187).

FDA approved the Dornier lithotripter for marketing in the United States on December 19, 1984 (187). The approved labeling of the lithotripter states that the device should not be used for patients who:

- have lower ureteral stones, bladder stones, or gallstones;
- cannot undergo either general or peridural anesthesia;
- should not be exposed to radiation, such as pregnant women;
- have an anatomy that precludes adequate imaging to focus the stone, such as patients with curvature of the spine or excess body fat;
- have a urinary obstruction below the position of the stone;
- have a pacemaker; or
- have renal artery calcification on the side to be treated (187).

This labeling limits Dornier's promotion of its ESWL device to treatment of kidney and upper ureteral stones. FDA regulations prohibit Dornier from labeling the lithotripter for a new use, such as treatment of stones in the lower ureter, without further proof of the device's safety and efficacy when employed for that purpose. However, FDA cannot prevent physicians from using the Dornier lithotripter for such a use.

The approval of the Dornier lithotripter was announced with great fanfare. The Department of Health and Human Services (DHHS) held a press conference that extolled the virtues of the lithotripter and that was attended by both the Secretary of DHHS and the FDA Commissioner. The device was described by the Secretary as an "authentic modern miracle" that would both lower costs and enhance quality of care (186); it was heralded by the press with headlines such as "Kidney-Stone Crusher Hailed" (143) and "Lithotripsy Smashes Kidney Stones and Health Care Costs" (91).

The FDA regulatory process probably did little to hinder the introduction of ESWL in the United States. Dornier received approval to conduct clinical trials into the United States in April 1983 (203), but the company did not begin them until early 1984 simply because it had no machines to deliver (125). The Dornier lithotripter's brief investigational period in the United States was probably as important to introducing the device to U.S. medicine and potential purchasers as it was to providing additional data to FDA. It is ironic that this technology, which had a relatively smooth passage through the FDA regulatory process, should be later cited as an example of FDA bureaucracy and overregulation. One commentator has called FDA to task for the fact that the Dornier lithotripter "had already been used for two and a half years in West Germany before the FDA bureaucracy began to evaluate it" (61), despite the fact that FDA had no jurisdiction over ESWL until the manufacturer decided to take steps toward marketing the device in the United States.

SAFETY AND EFFICACY OF ESWL: CURRENT STATUS

ESWL has already emerged as the preferred treatment among many urologists for most upper urinary stones (54,133). This enthusiasm is based on data showing up to 95 percent effectiveness in eliminating stones in patients for whom ESWL is selected, when ESWL is used either as a single modality or in conjunction with other techniques (22,57,90,137). The complete avoidance of a surgical incision and the short period of convalescence adds to ESWL's attractiveness and have been featured in well-publicized reports of patients who have undergone the procedure (28).

During 1984, more than 7,000 ESWL treatments were performed around the world, including about 2,400 procedures at six centers in the United States (11). By October 1985, over 50,000 treatments at over 90 ESWL centers worldwide had been performed (81), and the number has continued to climb. As mentioned above, the available data on the world experience to date indicate that up to 95 percent of patients are free of stones 3 months after ESWL. An adjunct procedure is necessary in 10 to 25 percent of patients to achieve this degree of success, and 10 to 15 percent require more than one ESWL session. Recurrence rates with ESWL of new symptomatic stones have not been reported. Also, the role of medical management and preventive measures after ESWL has not been addressed in the literature.

The U.S. experience reported in the literature appears to corroborate the German reports used as the basis for Dornier's application to FDA. At Methodist Hospital in Indianapolis, 500 patients had undergone ESWL treatments for stones in the kidney and ureter by July 1985; only 14 percent were completely stone-free at discharge from the hospital, but at 3 months 75 percent had no radiographic evidence of stones (90). The proportion requiring secondary stone manipulations was 7.5 percent, but only five patients required a percutaneous approach. Repeat ESWL was necessary in 9 percent. Open surgery for stone removal was necessary in one patient (90).

Researchers in the New York Hospital-Cornell University ESWL unit have reported that, in 467 patients undergoing 518 treatments, 92 percent of disintegrated stones passed spontaneously after ESWL (138). Twenty-three percent of treatments required prior cystoscopic procedures, with FDA category B stones more likely to need these procedures (137). (These stones include those that are greater than 2 cm, are located in the ureter, are partial or complete staghorns, and are accompanied by infection). Seventy-five percent of patients were stone-free after 3 months. Complications included colic, vomiting, infection, and one symptomatic perirenal hematoma requiring blood transfusion (137).

A West German group has recently reported on 750 patients receiving ESWL treatments; stone disintegration was achieved in 99.1 percent, while 0.6 percent underwent percutaneous nephrolithotomy alone and 0.3 percent open surgery (57). Immediate secondary measures were necessary in 16 percent, including repeat ESWL treatments. X-ray evaluations 3 months after ESWL showed that 85 percent of patients were stone-free; a second ESWL session was required in 3 percent of cases (57).

Open surgery for stone disease will likely be used for relatively few patients in the future. Percutaneous nephrostomy with ultrasonic lithotripsy, the most likely alternative to ESWL for upper urinary stones, is effective in 95 percent of upper urinary stone cases but carries a risk of serious complications greater than that for ESWL. Bleeding from trauma to vascular structures occurs in 1 percent of percutaneous nephrostomy cases (120) compared to an approximately 0.6 percent incidence of similar complications (usually perirenal hematomas) from ESWL (27). On the other hand, concomitant procedures are more likely to be necessary with ESWL than with percutaneous nephrolithotomy. ESWL is rapidly becoming the preferred treatment for many stones in the renal pelvis or calices that cannot be adequately treated with drugs, but percutaneous nephrolithotomy is also being widely adopted. The precise clinical indications for one treatment rather than the other, when only a single treatment modality is necessary, are still unclear.

Stones located in the ureter are more difficult to manage than stones in the kidney, and only those in the upper portion of the ureter are common candidates for ESWL. Some stones found initially to be in the lower ureter (below the iliac crest) can be moved, through transurethral manipulation, to the upper ureter or renal pelvis where ESWL is effective (105). Direct application of ESWL to lower ureteral stones is currently being tried on an experimental basis (82). Ureteral stones lodged in the same place for more than a few weeks are not removed effectively by ESWL (24,47). A combination of transurethral or percutaneous procedures and ESWL may be expected in a greater proportion of ureteral than renal stones (137).

ESWL, alone or in combination with secondary procedures, can remove over 85 percent of ureteral stones (137), but many of the advantages of the noninvasive procedure (ESWL) are lost when a second, invasive procedure (such as percutaneous ultrasonic lithotripsy) is required (155). Still, ESWL in combination with percutaneous stone removal is probably less tramatic than open surgery (89) and is likely to replace open surgery for many ureteral stones.

The U.S. experience with ESWL offers one encouraging fact: many of the adjunct manipulations have been transurethral and not percutaneous. This fact may be due in part to the use of prior transurethral manipulation of ureteral stones to make them amenable to ESWL treatment. Nevertheless, emphasizing transurethral rather than percutaneous approaches can limit the risks involved with adjunct procedures performed before or after ESWL, since transurethral manipulations are considerably safer than are percutaneous procedures (155).

The safety of ESWL in the short run has been well established, and morbidity from the procedure compares favorably with open surgery and percutaneous techniques (88). Some patients have pain when passing the fragments, which may be treated with oral or intramuscular medication, and some morbidity from anesthesia is expected (155); one patient in the United States has died from anesthesia complications (203). Radiation from the X-ray system is a concern, but it is less per treatment than with percutaneous lithotripsy (58). Furthermore, it is comparable to the radiation required to visualize a stone before and during open surgery[3] if ultrasound rather than X-rays are used for post-ESWL imaging (58).

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[3] Radiography is sometimes used to identify the location of a stone during surgery. Intraoperative ultrasonography is also occasionally used (98).

The long-term effects of ESWL, including the effects on the kidney of repeated ESWL treatments, are still in need of study (155). One major concern regarding long-term effects is that between 10 and 25 percent of patients treated with ESWL still have residual stones (visible on plain X-rays) at 3 months (27,57,90,137). These fragments ("stone dust") may act as a nidus for new stone formation and lead to higher recurrence rates than would otherwise have occurred. Recurrence rates of 40 to 60 percent have been reported after open surgical procedures (100), implying that combining medical management and preventive measures with any surgical or ESWL treatment of stone disease is very important (130).

The majority of stones to be treated by ESWL will be calcium containing. Besides being the most frequent type of stone encountered, calcium stones are radiographically dense and often fairly small, making ESWL a likely first choice for therapy. ESWL may also be important in treating certain struvite stones, which can grow to enormous size. A combination of ESWL, and percutaneous lithotripsy has been proposed as the optimal therapeutic approach for many of these stones (89,137). Cystine stones are more difficult to treat with ESWL, because they are not as brittle as other stones and do not fragment as easily. Two groups have reported using chemolysis in combination with ESWL to disintegrate cystine and struvite stones (47,149).

The distribution of treatment modes used for urinary stones is still changing rapidly as more experience with both ESWL and percutaneous stone removal on a wider variety of patients (and with a wider variety of urologists performing these procedures) accumulates. For example, early ESWL treatments employed around 500 to 1,000 shocks per patient (26). An average of about 1,300 shocks per patient in the United States was reported in mid-1985 (11), and an average of 1,600 shocks per patient in 16 surveyed hospitals was reported in April 1986 (40), indicating that increasingly more difficult stones are being successfully treated with ESWL. The average may continue to climb as more centers regularly perform ESWL on difficult stones; or, it could stabilize or even decline if patients with simple stones who would not have been recommended for surgery in the past nevertheless are recommended for the less traumatic ESWL. A likely scenario is that both percutaneous and extracorporeal lithotripsy will be employed as an alternative to open surgery for many patients with very large or difficult stones.

The role that ESWL may play in the management of urinary tract stones is illustrated by the experience of the Stuttgart, West Germany Stone Clinic. During the first 11 months after the introduction of an ESWL unit, 1,302 patient were treated and 762 (58.5 percent) received ESWL (105). Kidney stones were found in 877 patients, and 77.5 percent of these were treated with ESWL alone. An additional 19 percent of kidney stone patients were managed with a combination of ESWL and percutaneous nephrolithotomy. ESWL treatment of ureteral stones was limited to those located above the iliac crest, and thus ESWL was applied in only 19.3 percent of ureteral stones. A total of 80 patients (6.1 percent) required open surgery. The referral nature of the Stuttgart patients limits the applicability of this experience to the general population of patients with upper urinary stones. The Stuttgart report, however, does bear out the central role of ESWL in the management of stone disease.

The Stuttgart experience can be contrasted with the experience of an American hospital with ESWL during the investigational phase of the Dornier lithotripter in the United States. Researchers from this hospital reported the following distribution of alternative treatments among 304 patients: 37 percent received simple one-treatment ESWL, 35 percent required a second ESWL treatment or a supplementary transurethral manipulation, 13 percent received simple percutaneous nephrolithotomy, 10 percent received percutaneous nephrolithotomy with or without adjunct ESWL to treat staghorn stones, and 4 percent required open surgery for stones (109). Thus, approximately three-quarters of upper urinary stone patients at this hospital were treated with ESWL during its introductory phase, either alone or in conjunction with other treatment modes.

These experiences suggest that open surgical procedures for upper urinary tract stones may well be reserved in the future for less than 10 percent of all patients requiring more than conservative medical management. What is not yet clear is the mix of ESWL and endoscopic procedures that will be used to treat the remaining 90 percent or more, and the extent to which the availability of these procedures will encourage more aggressive management of stones. No randomized clinical trials comparing ESWL to other treatments for upper urinary stones have been performed; such investigations could greatly assist medical decisions regarding the appropriate applications for the various alternatives.[4]

OTHER EXTRACORPOREAL SHOCK WAVE LITHOTRIPTERS

At least three U.S. manufacturers are developing ESWL devices, with quite a bit of diversity in components. As of December 1985, only one manufacturer (Medstone) had begun clinical trials (103). The devices, summarized in table 4, are expected to be cheaper and more versatile than the Dornier lithotripter, but whether they prove to be as effective remains to be seen. All of the devices under development use shock wave energy to fragment the stones, but they produce the energy in different ways. They differ in two other important ways as well: in the acoustic interface (whether the patient is actually in a water bath or whether some other means is used to convey the shock wave) and in the imaging equipment used. Since precise imaging is a vital component of ESWL, advances in imaging can have a substantial effect on the technology. An important factor to demonstrate in the clinical trials of ESWL devices under development is the ability of less costly equipment to produce a rapid and accurate image of a stone's position.

Table 4.—Extracorporeal Shock Wave Lithotripters Under Development in the United States, December 1985

	Developer		
Characteristics	Medstone International	Northgate Research	International Biomedics
Shock wave generator	Spark gap	Spark gap	Laser
Imaging system	X-ray	Ultrasound	X-ray
Acoustic interface	Fluid-filled bag	Fluid-filled bag	Water-filled chest waders
State of development	Clinical trials	Animal studies	Animal studies

SOURCES: American Urologic Association, *Report to the American Urological Association Ad Hoc Committee To Study the Safety and Clinical Efficacy of the Current Technology of Percutaneous Lithotripsy, and Non-Invasive Lithotripsy* (Baltimore, MD: AUA, May 16, 1985); G. Clisham, Medstone International Inc., San Diego, CA, personal communication, October 1985; W. Shene, Monaghan Medical, Plattsburgh, NY, personal communication, November 1985.

The impacts on these new devices of FDA premarket requirements are twofold. First, they ensure that future ESWL devices on the U.S. market will meet some standard of safety and efficacy. Second, they force developers to consider the time necessary to conduct scientifically valid clinical trials when anticipating the speed with which the developers can introduce their devices on the open market. All new ESWL devices must undergo extensive clinical testing before FDA approval. With the possible exception of Medstone's device, which could conceivably be awarded premarket approval in late 1986, none of the U.S. lithotripters is likely to be available for general marketing before 1987. Even Dornier, which submitted its premarket approval application largely on the basis of 4 years of West German data, had its device in clinical trials in the United States for 10 months before the lithotripter received formal premarket approval.

There are qualifications to both of these impacts. Although FDA standards require a certain level of safety and efficacy, they do not affect other aspects of a device related to quality, and the future spectrum of ESWL devices may demonstrate a range of differences in attributes such as imaging clarity and average time required per procedure. The potential cost vs. quality tradeoffs of alternative ESWL devices cannot be evaluated in advance. Also, the necessity of conducting thorough clinical trials for FDA purposes will not slow the development of alternative devices whose manufacturers would have conducted trials for marketing purposes in any case. FDA regulations do not prevent manufacturers from distributing some ESWL devices before premarket approval, because they permit the distribution of devices necessary to conduct the clinical investigations. Still, the FDA premarket approval process acts to ensure that Dornier is the only unrestricted seller until the next ESWL device obtains approval. Thus, Federal policies that regulate the marketing of medical devices could ultimately have some effect on the overall distribution of the Dornier lithotripter relative to other ESWL devices. The primary determinant of distribution, however, will probably remain Dornier's advantage of being the initial manufacturer of the device.

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[4] In a randomized clinical trial, patients with a common condition (e.g., a kidney stone of particular size and type) are randomly assigned into two or more treatment groups. Statistical tests can then be perfomed on the aggregate results of the treatments to determine which is more effective (177).

U.S. manufacturers are not alone in developing new ESWL devices; other manufacturers around the world are also developing products for the ESWL market. For example, Yachiyoda Industry in Japan is working on a water bath ESWL unit (1). The use of microexplosive pellets for endoscopic lithotripsy, described briefly in chapter 3, is a Japanese innovation with potential application to ESWL.

A French company, EDAP, is developing a unit that uses ultrasound imaging equipment and a water-filled pouch instead of a bath to transmit the shock waves (2). The shock waves in the French device are produced by a series of piezoelectric transducers,[5] which need not be frequently replaced. If this method of wave generation proves to be effective, it may be less expensive than the spark-gap generator used by most other manufacturers to produce the wave energy.[6] EDAP is currently conducting clinical trials in France and expects marketing approval in that country to be imminent; it anticipates beginning clinical trials in the United States in 1986 (2). A second French company has recently announced the development of its own ESWL device (110). Given the anticipated market for ESWL in the world, it is likely that other manufacturers are investigating ESWL as well.

Research on extended applications of ESWL is rapidly expanding. The current model of the Dornier lithotripter is in clinical trials in the United States for use on lower urinary stones (82), and a new model to be applied to gallstones is undergoing clinical trials in West Germany (93,147). In addition, U.S. researchers have discovered that shock waves can destroy cancer cells *in vitro* and delay tumor growth in animals, a finding with potentially significant medical implications (144). Applications such as the use of shock waves to treat arteriosclerotic plaque are other promising areas of research (173).

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[5] When voltage is applied to a piezoelectric transducer, it causes a crystal in the transducer to expand. Shock waves can be created by the repeated expansions and contractions of this crystal.

[6] The spark-gap electrode in the Dornier lithotripter usually must be replaced at least once during each procedure; Medstone's electrode is predicted to need replacement for each new procedure (11,31).

Chapter 5

The Costs and Economics of ESWL

Chapter 5

The Costs and Economics of ESWL

INTRODUCTION

The costs and economics of providing extracorporeal shock wave lithotripsy (ESWL) are central to public policies regarding this technology. Lower provider costs can lead to lower health care expenditures, an important goal of payment policies. Also, to the extent that the total system costs of ESWL are minimized, resources are freed for other uses. The interaction between provider costs and public policies works both ways; the decisions of health care payers and planners can affect the cost of providing ESWL, because these policies influence decisions to purchase and use the technology.

ESWL equipment is very expensive to purchase and maintain. Consequently, if only a few patients are treated, the cost to the ESWL center of treating each patient is high; as more patients are treated, per-patient costs decline. But the economics of ESWL involve more than a consideration of facility costs. Professional costs are also vital because patients are referred to ESWL centers by physicians, and physicians perform the procedure. Physicians' access to ESWL and their income from performing ESWL relative to other treatment technologies, which depends on relative costs and payment rates, affect their willingness to recommend and perform ESWL treatment.

As background for the discussions of payment and planning policies and their implications, this chapter reviews the available literature on the current costs of ESWL to hospitals, physicians, and other providers, and to some extent to patients.[1] Constraining this review is the fact that the literature on ESWL costs is very sparse, and the fact that the resource costs of many of the components of hospital and physician services are unknown or controversial. For example, the dollar value of costs such as physician time can be calculated in several ways; a physician's own charges can be interpreted (after accounting for overhead) as the value that he or she places on the time spent providing a service. Consequently, charges are often used in the medical literature as a proxy measure of costs. The proxy may sometimes be a very poor one, and the charges reported here do not necessarily indicate the actual input costs to physicians, hospitals, or other facilities of providing any one technology. Charges as well as costs are nevertheless discussed in this chapter because in many cases they are the only cost-related information available, because they may give some indication of the relative costs of providing one technology compared to another, and because they matter to many payers of health care services.

The costs of providing ESWL vary greatly with the number of patients treated, the site of care, the device used, and the mix of physicians and technicians performing the procedure. The first part of this chapter reviews the major components of the costs of ESWL to the hospital or other purchaser and discusses the implications of ESWL's high fixed costs. The chapter then describes the costs and economics of physicians' ESWL services. Finally, it discusses comparative costs and charges for alternative technologies to treat upper urinary stones, including the disability time (hospitalization and recuperation) associated with ESWL and with its alternatives.

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[1] Unless otherwise specified, "cost," as used in this chapter, refers to the resource costs to the provider for the inputs purchased. Hospitals and other facilities purchase inputs such as supplies, employee time, and equipment; physicians' costs include time, educational expenses, and office overhead. "Charges" are the prices that providers (hospitals, ambulatory treatment facilities, and physicians) attach to their services and are not necessarily directly related to their costs. To complete the circle, what third-party payers actually pay to providers for these services is not necessarily equal to either providers' costs or charges.

COSTS TO THE HEALTH CARE FACILITY

The facility-related costs of ESWL can be divided into three categories: 1) the fixed capital cost of purchase and installation, 2) the costs of operating the machine, and 3) other institutional costs of caring for ESWL patients. These costs vary depending on the extent of renovation or construction necessary, the number of patients served, and the type of facility (such as a freestanding ambulatory clinic or a hospital). They will also vary, in the future, depending on which ESWL device is used.

Capital Costs

The two major components of fixed capital costs for ESWL are the cost of the machine itself and the cost of the facility to house it. Because the Dornier lithotripter is manufactured in West Germany, its cost varies somewhat according to the international exchange rate but has been approximately $1.7 million for the past year. The cost of an ESWL facility is much more variable, because it depends on the needs and goals of the hospital or other organizations that own it. The installation (construction and renovation) costs of the first six hospitals in the United States to acquire the device averaged $375,000 and ranged from $200,000 to $1,080,000 (3,11). In the latter case the new facility included not only a room to house the lithotripter but accommodations for a vastly expanded patient load, physicians' offices, and a 50-seat auditorium (3,82).

The installation costs of future hospitals acquiring ESWL will depend on the extent to which ESWL will expand (rather than replace) current services. If renovation of existing cystoscopy rooms and office space are sufficient, construction costs will be low. The American Hospital Association estimates that most future hospitals can adapt their facilities for ESWL at a cost of about $250,000 (3). Dornier itself has estimated that, when only renovation of existing surgical space is necessary, installation can be performed for as low as $100,000 (14). The Blue Cross and Blue Shield Association chose to use a figure halfway between these two ($175,000) as its estimate (14). Considering these and the previous figures, it is reasonable to assume that the total fixed, capital cost of purchasing and installing a Dornier lithotripter at present is around $2 million. A lithotripsy center requiring substantial new construction, of course, would have higher costs.

Following standard practice, current estimates assume a 5-year life of the present machine (14). The Blue Cross and Blue Shield Association estimated interest expenses in 1985 at an additional $219,000 per year (14) (see table 5).

The anticipated lower purchase and installment costs of second-generation ESWL devices are a major selling point for their manufacturers. An important point to note is that some of these devices are expected to lower the installment costs of ESWL because they do not require a separate room, devoted to ESWL, to house the devices; they can be used in established surgical suites. The purchase costs are also expected to be lower than for the Dornier device, although since only Medstone had installed one in a U.S. hospital as of December 1985, the extent of savings is still uncertain. Medstone expects to price its device at approximately $850,000 (31). Northgate plans to price its device at approximately $400,000 (153). EDAP's lithotripter is tentatively priced at around $500,000, depending on the exchange rate (2,49). The effectiveness of these devices compared to the Dornier lithotripter cannot be known until they have been tested on a number of patients.

Operating Costs

Compared to fixed capital costs, the costs of operating an ESWL device probably will change somewhat less with the advent of the smaller devices. Typical costs of operating a lithotripter unit include the costs of technical and nursing staff, administration, insurance,[2] supplies (such as X-ray film, electrodes, and anesthesia), and the maintenance contract for the machine. The cost of a maintenance contract and the cost of the

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[2] In addition to the insurance that the owner of an ESWL device and facility carries to protect itself, Dornier requires that purchasers of its lithotripter indemnify the manufacturer against any liabilities not attributable to Dornier's own negligence (81).

Table 5.—Two Estimates of Hypothetical Annual Facility Costs of the Dornier Lithotripter, 1985

	Cost estimates				
	American Hospital Association		Blue Cross and Blue Shield Association		
Input	800 cases/year	1,000 cases/year	1,000 cases/year	1,500 cases/year	2,000 cases/year
Capital costs:					
Interest	$120,000	$120,000	$219,000	$219,000	$219,000
Depreciation (equipment and facility)	40,000	400,000	365,000	365,000	365,000
Subtotal	520,000	520,000	584,000	584,000	584,000
Capital cost per case	650	520	584	389	292
Technical operating costs:					
Salaries for additional full-time employees[a]	$131,000	$131,000	130,000	130,000	130,000
Insurance	75,000	75,000	75,000	75,000	75,000
Office and building expenses	26,000	26,000	30,000	30,000	30,000
Lithotripter annual service contract	188,500[b]	271,500[b]	117,500[b]	117,500[b]	117,500[b]
Electrode costs (est. $300/procedure)	240,000	300,000	300,000	450,000	600,000
Medical supplies (est. $30/procedure)	24,000	30,000	30,000	45,000	60,000
Collection fee[c]	192,000	240,000	—	—	—
Subtotal	864,000	978,000	655,500	807,000	958,500
Technical operating cost per case	1,080	978	656	538	479
Total technical cost	$1,384,000	$1,498,000	$1,239,500	$1,391,000	$1,542,500
Total technical cost per case	1,730	1,498	1,240	927	771
Ancillary and routine operating costs:					
Ancillary services per case	—	—	300	300	300
Routine inpatient services per case	—	—	800	800	800
Total operating costs per patient			$1,756	$1,638	$1,579
Total facility costs per patient			$2,340	$2,027	$1,871

[a] Includes salaries and benefits for additional nursing, technical, and administrative personnel. Does not include physician salaries or charges.

[b] As of December 1985, Dornier's quoted price for a maintenance contract was $87,000 for the first year and $125,000 for each subsequent year, yielding an average of $117,500 over 5 years.

[c] "*Collection fees* are assumed to be the gross revenue less uncollectible charges, multiplied by 10 percent; which amounts to $240 per case. This is the fee the hospital's patient billing department may impose on a lithotripter treatment center that is not integrated with the hospital, such as a free-standing, outpatient treatment center" (3).

SOURCES: H.C. Alder, *Lithotripters: Noninvasive Devices for the Treatment of Kidney Stones*, AHA-012828 (American Hospital Association, Chicago, IL), 1985; Blue Cross and Blue Shield Association, *Extracorporeal Shock Wave Lithtripsy: Clinical Assessment, Utilization and Cost Projections* (Chicago, IL: BC/BSA, May 1985).

energy source (the electrode, in the Dornier device) are the operating costs most likely to vary among different ESWL models. For example, Dornier charges $200 per electrode for small orders and $160 per electrode for large orders (2,000 or more) (125). At present, ESWL requires approximately two electrodes per patient. In contrast, Medstone plans to charge $750 per patient for electrodes for the first 300 patients served by a unit and assumes a use of one Medstone electrode per patient. The price will decrease to $500 per patient for the second 300 patients, $250 for the third 300, and $100 for each patient after (31). Other methods of generating the shock wave, or longer lasting, inexpensive spark-gap electrodes, might lower operating costs further.

Preliminary and follow-up lab tests, X-rays, and routine hospital care (when the patient is hospitalized) are additional costs of caring for ESWL patients. Adjunct procedures, such as placement of a ureteral catheter, may also raise costs. Some of these costs may change as experience with ESWL technology increases, but they are not likely to be greatly affected by alternative devices currently under development unless those devices differ significantly in effectiveness from the Dornier lithotripter and require a different level of patient care.

Effects of Patient Caseload

The most important aspect of the cost to the facility of providing ESWL, other than the fact that it is high, is that it declines dramatically as caseload (the number of patients served) increases. This characteristic of ESWL is largely due to the high fixed costs of purchasing and installing a lithotripter, costs faced by a hospital or other lithotripsy facility regardless of how many patients are actually treated (although the costs might be slightly higher if the initial planned caseload was high). The consequence of this characteristic is that, at high volumes and constant per-case revenues, providing ESWL can be a very profitable venture[3] as well as an advancement in treatment alternatives and quality of care. Methodist Hospital of Indiana, for example, estimated that during its first year of offering ESWL it realized a profit of $400 per case (92). This potential profitability of ESWL makes it very attractive to many hospitals and physician groups. Ironically, if many facilities provide the technology, the caseload of each facility will be low, and few may actually realize those profits. Even so, a hospital might choose to acquire an ESWL unit and accept little or no profit per case if, by doing so, it could avoid losing patients to competing providers.

Two independent estimates of the total facility-related costs of providing ESWL, for a hypothetical hospital-based ESWL facility, are summarized in table 5. These hypothetical costs of an efficient facility can be contrasted with the average reported operating costs of several hospitals with ESWL units, as summarized in table 6. Clearly, the actual operating costs of these latter hospitals were substantially higher, with most of the difference in the routine and ancillary costs. A substantial portion of these high ancillary costs may be due to the requirements of the investigational protocol when ESWL was first introduced, since the early ESWL centers were included in the surveyed hospitals in table 6.

Table 6.—Average Per-Case ESWL Operating Costs of Hospitals As Reported in Two Surveys, 1985

	Prospective Payment Assessment Commission[a]	Georgetown University[b]
Number of hospitals surveyed	7	16
Utilization:		
Number of cases/year	1,200[c]	1,042
Number of ESWL shocks/case	1,100[c]	1,594
Operating costs per case:		
Technical costs	$ 667	$1,163
Room	777	637
Other services	1,268	1,320
Total	$2,712	$3,120

[a] Figures used by the Prospective Payment Assessment Commission are, with the exception of utilization assumptions, derived from costs reported by seven of the first hospitals to establish ESWL units in the United States (19).

[b] Figures used by Georgetown University are average reported costs of treating Medicare patients, from a survey of 16 hospitals (131).

[c] Utilization figures used by the Prospective Payment Assessment Commission are not actual figures reported by the hospitals, but rather are assumptions derived from data provided by the American Urological Association and the American Hospital Association (19). The fact that the Commission's assumed figures are higher than Georgetown's actual utilization averages may account for Georgetown's higher technical costs, which are sensitive to caseload.

SOURCE: Prospective Payment Assessment Commission, *Report and Recommendations to the Secretary, U.S. Department of Health and Human Services* (Washington, DC: U.S. Government Printing Office, Apr. 1, 1986).

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[3] "In economic theory, profits are expected to be just high enough to induce suppliers of a product to stay in the market to meet the demand. In a perfectly competitive industry, where entry and exit are entirely free and no artificial pricing policies are followed, profits would tend to stay at the minimum level. Excess profits higher than that level can occur when the producers of a service have some measure of monopolistic power" (181).

To the extent that serving a very large caseload requires additional construction and facilities, the decline in per-case costs as patient load increases that is demonstrated in table 6 may be overstated. However, it is notable that even substantial increases in the estimated costs presented in this table have only a small effect on per-case costs. For example, for a facility serving 1,500 patients per year, actual annual costs that were $100,000 higher than the costs estimated by the Blue Cross and Blue Shield Association (see table 5) would increase per patient costs by only $67, from $2,027 to $2,094.

That the first hospitals to provide ESWL are probably all profiting from offering this service is evident from comparing table 6 with table 7, which lists the 1985 charges for ESWL treatment (not including charges for physician, ancillary, or inpatient care services) at each of the first six institutions to furnish it. There is no clear pattern between caseloads and charges for these hospitals.

Ambulatory Centers

One strategy for lowering ESWL-associated facility costs, attractive to many current and potential ESWL providers, is to lower or eliminate the patient care costs associated with a hospital stay. From its introduction in the United States until June 1985, ESWL was performed almost exclusively as a hospital inpatient procedure, in which the patient was hospitalized the day before the procedure and stayed in the hospital 2 or 3 days afterward for observation. Fewer than 3 percent of all treatments in the United States had been performed on ambulatory patients (no overnight hospital stay) as of May 1985 (11), and all existing ESWL units were in, or adjacent to, hospitals. In the future, ESWL could become an ambulatory procedure in a substantial number of cases, although the comparative quality of care when patients receive ESWL in this setting has not yet been assessed.

Table 7.—Approximate Average Technical Charges and Caseloads at the Six Longest-Operating Extracorporeal Shock Wave Lithotripsy Sites in the United States, May 1985

Hospital	Technical charge	Estimated patients per year
Methodist Hospital (Indianapolis, IN)	$1,600	2,000-2,200
University of Virginia Hospital (Charlottesville, VA)	2,800	1,800-2,000
Baylor University-Methodist Hospital (Houston, TX)	3,000	1,300-1,500
University of Florida-Shands Hospital (Jacksonville, FL)	3,000	900-1,100
New York Hospital-Cornell Medical Center (New York, NY)	3,600	1,100-1,300
Massachusetts General Hospital (Boston, MA)	4,050	1,000-1,200

SOURCE: Blue Cross and Blue Shield Association, *Extracorporeal Shock Wave Lithotripsy: Clinical Assessment, Utilization and Cost Projections*, Chicago, IL, May 1985.

An obstacle to routine ambulatory use of ESWL is the need for patients to have rapid access to emergency health facilities if complications arise or intramuscular pain medication becomes necessary. In one of the first U.S. hospitals to offer ESWL, for example, 6 of 315 ESWL patients were treated as outpatients, but 2 of these were subsequently readmitted to the hospital for relief of pain that did not respond to oral medication (11). If a large number of patients must be treated in emergency rooms, or must be admitted to the hospital, the extent and cost savings of ambulatory treatment may be far less than currently anticipated.

Nonetheless, three free-standing extracorporeal lithotripsy facilities that intend to treat primarily ambulatory patients opened in 1985, and thus far these facilities have succeeded in avoiding hospitalization for the great majority of their patients (86). For example, the first of these, a free-standing facility in northern California that opened in June 1985, treated 277 patients, ranging in age from 14 to 77 years, between June 20, 1985 and October 1, 1985. Twenty-five of these patients (12.1 percent) were admitted to a hospital after treatment (86). Patients at this facility are referred by their urologists, visit the facility on the day preceding treatment, and may either return home or stay at a local hotel the evening after treatment (68). The facility charges approximately $7,200 for a simple ESWL treatment, including the physician's fees (68), and was treating about 20 patients per week after 2 months in operation (86).

IMPLICATIONS OF HIGH FIXED COSTS

The high fixed costs of ESWL have important implications for its financial costs and benefits, both when it is considered alone and when it is compared with alternative technologies. If there are many ESWL centers, each one will treat fewer patients, have higher per-patient costs, and probably require more payer expenditures than would otherwise be the case.

As large numbers of patients are treated at an ESWL facility, costs decline for two reasons. First, and most importantly, the capital costs of purchase and installation are spread across a larger number of individuals. The effect of spreading costs is evidenced in table 5, which demonstrates that doubling caseload could reduce per-case technical costs for the procedure by as much as one-third. Second, the unit cost of electrodes for the Dornier lithotripter—a significant component of operating costs—declines if the electrodes are purchased in large volumes.

The direct association between volume of use and per-case cost of ESWL has prompted a number of individuals and organizations to estimate the number of ESWL centers that can or should be established, given a large caseload (and thus lower costs) at each center. As indicated in chapter 2, the number of patients with urinary stones who might be treated with ESWL rather than surgery could be as low as a small proportion of the 65,000 patients per year who undergo surgery on the upper urinary tract; it could be as high as the roughly 874,000 patients per year who are diagnosed with some type of urinary stone. Estimates of a number for whom ESWL might be reasonable and necessary range from 26,000 to 140,000, all based on patients hospitalized with stones but varying depending on the proportion of these for whom ESWL is judged to be appropriate. Similarly, an appropriate caseload for an ESWL center has been assumed to be as low as 800 patients treated per year (11,71) and as high as 2,000 patients (14). (The first figure is actually quite low, and the latter is by no means a practical maximum; a few hospitals are already serving 2,000 or more patients per year.) On the basis of these estimated caseloads, the number of ESWL centers required in the United States to treat patients who would otherwise require invasive treatment has been estimated at between 17 and 175 (11,155).[4] These estimates are summarized in table 8.[5]

The importance of these estimates is not the actual quantities but their use as a baseline comparison and as an indication that the number of devices needed to serve the population with stones requiring aggressive treatment is not large. The estimates offer a stark contrast with the reality: Dornier had delivered 50 lithotripters to hospitals in the United States by the end of 1985, and the company plans to have a total of about 100 installed by the end of 1986 (125). The locations of the ESWL units installed through December

Table 8.—Estimates of Number of Extracorporeal Shock Wave Lithotripters Required in the United States

	Estimated lithotripters required		
	Low	Middle	High
U.S. Department of Health and Human Services	—	100	—
American Hospital Association	28	—	48
American Urological Association[a] (1)	—	100	—
American Urological Association (2)	42	—	170
American Urological Association (3)	45	—	175
Blue Cross and Blue Shield Association	28	50	93
Showstack, et al.	17	—	106

[a] The American Urological Association estimated the number of lithotripters required under several different assumptions.

SOURCES: H.C. Alder, *Lithotripters: Noninvasive Devices for the Treatment of Kidney Stones* AHA-012828 (American Hospital Association, Chicago, IL, 1985); American Urologic Association, "Summary and Recommendations of the Ad Hoc Committee To Study the Safety and Clinical Effectiveness of the Current Technology of 1) Percutaneous Lithotripsy, and 2) Non-Invasive Lithotripsy," presented to the American Urologic Association as a Preliminary Report, New Orleans, LA, May 9, 1985, unpublished mimeo; Blue Cross and Blue Shield Association, *Extracorporeal Shock Wave Lithotripsy: Clinical Assessment, Utilization and Cost Projections*, May 1985; *HHS News*, statement by Margaret M. Heckler, Secretary of Health and Human Services, Dec. 19, 1984; Showstack, J.A., Perez-Stable E.J., and Sawitz, E., "Extracorporeal Shock Wave Lithotripsy: Clinical Application and Medicare Physician Payment," paper prepared for Office of Technology Assessment, Aug. 1, 1985.

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[4] The lowest estimate of ESWL units needed (17) was based on an estimated 26,000 patients undergoing surgery for upper urinary stones but used only 1,500 patients as an appropriate caseload. Applying a caseload of 2,000 patients per year, used in a separate estimate, to this number of eligible stones would yield a minimum of 13 ESWL units needed in the United States.

[5] The American College of Physicians has recommended regionalization of ESWL but has not specified an "appropriate" number of devices (5).

1985 are given in table 9. A notable point from this table is that while 26 States did not yet have an ESWL unit by the end of 1985, 13 States already had more than one.

The decreases in per-case costs that accompany increases in caseloads provide a strong incentive for hospitals to attempt to increase the number of patients using this treatment. If a large number of devices are purchased and their services offered to patients, per-case costs to the ESWL center will rise unless other stone patients, who would not previously have been considered for surgery, are treated. The high estimate of 874,000 newly diagnosed stones each year indicates how large this potential market could be. ESWL centers will have strong incentives to encourage physicians to prescribe ESWL treatment for patients who formerly would have been treated medically. Rather than being treated conservatively with pain medication and fluids, patients with newly diagnosed stones and in acute pain may be scheduled for immediate ESWL, regardless of the size of the stone. Indeed, at least one hospital already offers ESWL on this basis to some patients (82).

Table 9.—Dornier Lithotripters Installed in the United States as of December 1985

State	City	Purchaser
Alabama	Birmingham	AMI-Brookwook Medical Center
	Mobile	Springhill Health Service
Arizona	Phoenix	St. Joseph's Hospital
Arkansas	Little Rock	St. Vincent Infirmiry
California	Burbank	St. Joseph Medical Center
	Glendale	Glendale Adventist Hospital
	Long Beach	VHA—Memorial Medical Center
	Los Angeles	University of California
	Los Gatos	NME—Community Rehabilitation Center
	San Francisco	University of California
	San Jose	Los Gatos Medical Center
	Tarzana	AMI—Medical Center of Tarzana
Florida	Fort Lauderdale	North Broward Hospital
	Orlando	Florida Medical Plaza
	Gainesville	University of Florida
Georgia	Atlanta	Georgia Baptist Hospital
	Atlanta	Emory University
	Macon	HCA—Coliseum Park Hospital
	Savannah	Memorial Medical Center
Illinois	Chicago	University of Chicago
	Chicago	Rush Presbyterian/St. Luke's Hospital
	Peoria	St. Francis Medical Center
Indiana	Indianapolis	Methodist Hospital
Iowa	Iowa City	University of Iowa
Kentucky	Louisville	Humana—Suburban Hospital
Louisiana	New Orleans	VHA—Ochsner Foundation Hospital
	New Orleans	Tulane University
Massachusetts	Boston	Massachusetts General Hospital
	Burlington	Lahey Clinic
Michigan	Ann Arbor	University of Michigan
	Detroit	VHA—Henry Ford Hospital
Minnesota	Minneapolis	University of Minnesota
	Rochester	Mayo Clinic
Missouri	St. Louis	Barnes Hospital
New Jersey	Marlton	Garden State Community Center
New York	New York	Cornell University/New York Hospital
North Carolina	Winston-Salem	North Carolina Baptist Hospital
	Winston-Salem	Hawthorn Medical Mall
	Durham	Duke University
Ohio	Cinncinati	Bethesda Oak Hospital
	Cleveland	Calicilex Corporation
	Columbus	Ohio Kidney Stone Management
	Toledo	Genito Urinary Surgeons
Pennsylvania	Philadelphia	University of Pennsylvania
Tennessee	Knoxville	HCA—Park West Hospital
	Nashville	VHA—Baptist Hospital
Texas	Dallas	Presbyterian Hospital
	Houston	The Methodist Hospital, Texas Medical Center
Virginia	Charlottesville	Virginia Kidney Stone Foundation
Washington	Seattle	Mason Clinic
TOTAL: 50 units		

Acronyms: AMI—American Medical International
HCA—Hospital Corporation of America
NME—National Medical Enterprises
VHA—Voluntary Hospitals of America

SOURCE: E. Polzer, Dornier Medical Systems, Marietta, GA, personal communication, October 1985.

COSTS AND ECONOMICS OF PHYSICIAN SERVICES

Physicians have both direct and indirect effects on the cost of ESWL to facilities and the payments for ESWL by patients and third-party payers. Physicians make the actual decision to refer or not to refer patients for ESWL, and thus they control the number of patients treated at each facility, which in turn affects both per-treatment and total costs. Because financial factors can influence physicians' decisions, the relative cost to physicians of performing alternative treatments has significant implications for the use of, and total costs for, ESWL. Financial incentives to treat patients with ESWL are especially powerful when the physician is a part owner of the ESWL center. And, finally, to the extent that payers attempt to adjust payments to costs, physicians' costs affect expenditures directly.

Physicians, with the exception of some hospital-based physicians, have traditionally billed for their professional services separately from the services provided by the health care facility. The actual costs of providing services are exceedingly difficult to define. Not only are the relative amounts of various inputs (surgical time, advisory time, administrative time, office overhead, etc.) difficult to determine, but the value of those inputs, and their relationship to physicians' charges, is an unending subject of debate.

At least three types of physicians may be involved in a lithotripsy case. The physician in charge of the patient is most likely to be a urologist, trained in the diagnosis, removal, and other treatment of urinary stones. Urologists currently perform most surgical stone removals and most percutaneous removals and transurethral manipulations. An anesthesiologist and a radiologist may also be involved in performing ESWL, although a nurse-anesthetist may provide anesthesiology services, and the radiologist's role may be largely confined to preprocedure diagnosis of the stone and radiological follow-up.

Whether physicians other than urologists should be in charge of some ESWL cases is a matter of debate. Nephrology, for example, is a subspecialty of internal medicine centering on disorders of the kidney. However, nephrologists have traditionally not performed surgical treatment of kidney stones, and there is resistance on the part of many urologists to permitting nephrologists to perform ESWL. In the short run, at least, it is unlikely that physicians other than urologists will be in charge of the ESWL procedure itself.[6]

The fact that only urologists are likely to be performing ESWL in the near future has implications for the costs of the procedure both to those who perform it and to those who pay for it. The cost to a urologist of performing ESWL can be thought of as the opportunity cost of not spending time in alternative ways, such as in performing open surgery or percutaneous lithotripsy. If ESWL takes time, training, and skill comparable to these alternatives, then its costs are comparable. At present, there are no data on these factors, although the little evidence available indicates that ESWL takes less time—usually an hour or less (137), compared to reported percutaneous or open surgery times averaging 2 hours or more (129). To the extent that a urologist can perform ESWL more quickly than alternative procedures, the costs of ESWL to the urologist are lower.

The time it takes physicians to perform ESWL (and, hence, their costs) are, like facility costs, sensitive to the volume of services provided. Physicians will not only increase their efficiency as they perform more procedures after learning the technique, but they are likely to continue to perform it both quickly and effectively if they perform it often.

Other professional costs associated with ESWL, such as patient evaluation and follow-up services, should be roughly comparable to those required for alternative procedures. These costs may even become lower over time, since ESWL should require fewer follow-up hospital visits by the physician due to the shorter hospitalization that ESWL requires. It has been noted that ESWL currently requires extensive patient-physician discussions that include informing the patient about the new technology and evaluating which patients are more suitable for a technique that is still novel. Over time, however, these costs should more closely approximate the routine evaluation necessary for any major treatment alternative.

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[6] The American Urological Association has recommended that only individuals ". . . who have expertise in surgical and endoscopic skills equivalent to those certified by the American Board of Urology; or, Urology residents in training . . ." operate a lithotripter (11). Since all training is currently done by ESWL-experienced urologists, nonurologists are unlikely to be permitted to train in ESWL in the near future.

Despite the fact that actual costs of ESWL to physicians performing it are probably lower than the costs of performing alternative procedures, and will probably decrease further, many urologists argue that charges for ESWL should be comparable to those for the surgical alternatives. Bases for this argument are, first, that ESWL requires substantial additional training on the part of the physician, and second, that ESWL replaces surgical procedures and should be charged a comparable price. These arguments carry the highest weight in the short run, when learning and evaluation costs are relatively high. However, as discussed in the next chapter on payment, price may not decline even after costs have done so. This problem makes the quantification of physician costs important to payers who wish to adjust relative payments to relative costs.

Box A presents a possible model for quantifying the costs to a urologist of performing ESWL. The model is based on opportunity costs to the physician, of which time is the most important. This example uses a surgical income (including benefits) of $218,750 per year as the basis for the value of time to a urologist. This income can be thought of as either the gross (before tax) income, after deducting office expenses, of a self-employed urologist, or as the gross income of a salaried urologist.[7] A crucial assumption of the model is that the physician values all time equally. If the time spent on services associated with ESWL is valued more highly than other time, or if the physician spends more time in preparation and evaluation than is allowed in the model, the model may undervalue the costs associated with ESWL patients. The surgical income base, however, may overvalue costs if there is a protechnology bias in the present reimbursement system (155). A lower income base would result in lower costs, since it represents a lower value for time.

Although this model relies on broad general assumptions that undoubtedly do not hold true in many cases, it does offer a basis for discussion for future estimates of the cost of performing ESWL-related services over time and for comparative costs among alternative technologies. Note that the model does not include the anesthetist's component of the total professional fee.

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[7] This number appears to be a reasonable but somewhat high approximation of gross personal income. An ongoing, self-reported survey conducted by *Medical Economics* found that average gross practice earnings for urologists in 1984 were $221,230 (116). The median professional expenses for this group were $78,060 (117), yielding gross personal earnings of roughly 143,170. Note that with lower earnings, the opportunity cost of spending time performing ESWL is also lower.

COMPARING COSTS OF ALTERNATIVE TECHNOLOGIES

Data in the existing literature do not permit direct comparisons of the costs of alternative technologies for treating upper urinary stones. Charges, however, have been compared across technologies at several institutions, with results that are occasionally surprising. Table 10, for example, presents charges for stone removal at two institutions. These institutions are in different States, and interinstitutional comparisons of charges may not be entirely appropriate, but the within-institution comparisons permit some interesting insights. At the institution that performs both ESWL and percutaneous lithotripsy, total professional charges for simple ESWL are substantially less than for simple percutaneous nephrolithotomy. This difference results not from lower fees by the urologist, but from the lower anesthesiology fees and the lack of need for a radiologist. However, ESWL savings disappear when more than one treatment or additional stone manipulation is needed; total professional fees are higher for complicated ESWL cases than for open kidney surgery for stones at this institution (11).

Researchers at a second institution compared charges for three different methods of perform-

Box A.—A Model of Physician Opportunity Costs of Performing ESWL[1]

Description of the Model

One way to estimate physician costs of performing ESWL is to calculate the opportunity costs to the physician of performing the procedure. It is perhaps easiest to understand this model if one thinks of a prepaid group practice calculating the number of procedures, including pre- and post-procedure visits, that could be completed by a urologist who is hired full time to perform ESWL.

It is assumed in this model that a physician provides patient care 35 hours per week for 46 weeks per year, totaling 1,610 patient care hours per year. This model includes both uncomplicated and complicated cases. A prototypical uncomplicated case might include:

- one prehospital office visit that includes a patient history and physical exam,
- a hospital visit,
- the procedure itself,
- two subsequent hospital visits after the procedure, and
- two office visits after hospital discharge.

The prototypical complicated case includes three additional visits in the hospital and two additional ambulatory visits as well as the visits and procedure outlined for the uncomplicated case.

The total amount of professional time calculated in this model to take care of an uncomplicated case is 5.0 hours; a complicated case is calculated to require 7.5 hours. The estimates of time include routine tasks, such as writing notes and taking phone calls. It is estimated that if all cases are uncomplicated, approximately 322 procedures per year could be performed by a urologist. If all cases were complicated, approximately 215 procedures per year could be performed.

The model assumes that the cost to the group practice of hiring a full time urologist to perform procedures is $175,000 per year salary, plus $43,750 in fringe benefits, for a total cost of $218,750.[2] Dividing this by the number of procedures per year implies that the actual opportunity cost to a urologist of performing ESWL full time, rather than spending it on other activities, is approximately $679 for an uncomplicated case and $1,017 for a complicated case. If most cases are uncomplicated, the typical cost per case might be approximately $800—approximately one-half the fee that a group practice would have to pay if a urologist were paid the same rate as urologists currently charge for open stone surgery (see table 10).

The model also assumes that a referring physician would transfer total responsibility for the patient or would perform the procedure and all followup visits him/herself. Malpractice insurance fees are assumed not to change as a result of substituting ESWL for other services and are therefore omitted from the model. The fees of an anesthesiologist are also omitted from the calculation.

The Calculation

Annual opportunity costs:

$175,000	presumed annual wages for a salaried urologist
43,750	fringe benefits (25 percent of salary)
$218,750	total income expected from alternative activities

Total time available: 35 hours/week × 46 weeks/year = 1,610 hours per year (assumes 5+ hours/week for continuing education, etc.; 6 weeks vacation per year)

Potential time devoted to ESWL and related activities:

	Uncomplicated case	*Complicated case*
Prehospital history and physical exam	1.0 hour	1.0 hour
Procedure	1.5 hours	1.5 hours
Hospital visits (0.5 hr. each)	1.5 hours	3.0 hours
Posthospital visits (0.5 hr. each)	1.0 hours	2.0 hours
Total	5.0 hours	7.5 hours

Cost per ESWL case:

Uncomplicated case: 1,610 hours/5.0 hours per case = 322 cases; $218,750/322 cases = $679 per case

Complicated case: 1,610 hours/7.5 hours per case = 215 cases; $218,750/215 cases = $1,017 per case

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[1] Adapted from J.A. Showstack, E.J. Perez-Stable, and E. Sawitz, "Extracorporeal Shock Wave Lithotripsy: Clinical Application and Medicare Physician Payment," paper prepared for the Office of Technology Assessment, Washington, DC, Aug. 1, 1985.

[2] In 1979, the most recent year for which American Medical Association data for urologists' earnings are available, the median net incomes for urologists in solo practice were $93,530 (for those in solo practice) and $99,060 (for those in partnerships) (7). The median net income for general surgeons in solo practice in this year was $96,000. Based on the reported rate of rise in general surgeons' incomes through 1982, the approximate median net income of a general surgeon in 1985 was $175,000; thus, this figure was used as an approximation of a urologist's median net income in 1985 (136).

Table 10.—Examples of Average Hospital Charges for Alternative Methods of Removing Upper Urinary Stones

Treatment	Hospital charges					Professional charges				
	Technical (operating and recovery room)	Room and routine care	Ancillary services and supplies	Other	Total	Urologist	Anesthesiologist	Radiologist	Total	Total charges
Methodist Hospital, Indianapolis:										
Simple one-treatment ESWL	$1,741	$ 951	$ 955	$184	$ 3,831	$1,515	$352	$ 0	$1,867	$ 5,698
Complicated ESWL (more than one treatment or additional manipulation)	3,006	1,623	1,626	307	6,562	2,179	822	0	3,001	9,563
Simple nonstaghorn percutaneous nephrolithotomy	2,148	1,488	1,334	53	5,023	1,597	650	500	2,747	7,770
Percutaneous nephrolithotomy for staghorn stone (may include ESWL in addition)	4,756	2,599	2,615	231	10,201	2,848	900	500	4,248	14,449
Anatrophic nephrolithotomy (open surgery for stones not treatable with other methods)	3,122	3,131	3,399	120	9,772	1,812	950	0	2,762	12,534
University of Texas Health Science Center, Dallas: (no ESWL unit)										
Outpatient percutaneous nephrolithotomy					1,254				2,095	3,349
One-stage percutaneous nephrolithotomy					2,359				2,030	4,389
Two-stage immediate percutaneous nephrolithotomy					4,926				2,588	7,534
Two-stage delayed percutaneous nephrolithotomy					2,321				2,169	4,490
Open surgery					4,182				2,370	6,552

SOURCES: American Urologic Association, *Report of American Urological Association Ad Hoc Committee To Study the Safety and Clinical Effectiveness of the Current Technology of Percutaneous Lithotripsy, and Non-Invasive Lithotripsy* (Baltimore, MD: AUA, May 16, 1985); G.M. Preminger, R.V. Clayman, T. Curry, et al., "Outpatient Percutaneous Nephrostolithotomy," unpublished paper abstracted in *J. Urol.* 133(4):316A, April 1985 (part 2); G.M. Preminger, R.V. Clayman, and S.W. Hardeman, "Percutaneous Nephrostolithotomy vs. Open Surgery for Renal Calculi," *J.A.M.A.* 254(8):1054-1058, Aug. 23/30, 1985.

ing percutaneous nephrolithotomy with open surgery on patients with equivalent stones (130). They found that professional charges for percutaneous procedures were slightly less than for open surgery except when percutaneous nephrolithotomy was performed as a two-stage immediate procedure (see ch. 3). Professional charges at this institution and the one also providing ESWL cannot be compared precisely, because the patients may not have been equivalent across institutions. It is notable, however, that total professional fees for simple ESWL at the one institution are lower than professional fees for any percutaneous or open surgery performed at the institution without ESWL.

To the extent that relative charges do reflect relative costs to the hospital, the hospital average charges from Methodist Hospital in Indianapolis, summarized in table 10, indicate that simple ESWL treatment is less expensive to that hospital than percutaneous or open surgery. However, if additional ESWL treatments or stone manipulation is needed, the cost savings of ESWL to the lithotripsy center may be lost.

The above discussion suggests that patients with stones that can be treated with a single ESWL procedure may have lower total charges (facility plus professional) than if they underwent either percutaneous or open surgery. But some percutaneous nephrolithotomy patients at the University of Texas hospital have lower charges than patients undergoing simple ESWL at the Indianapolis hospital. Since the patients and the charges at these two institutions are not directly comparable, no firm conclusion can be drawn regarding these two technologies. Nor is it clear which alternative is less expensive in total for complicated stones, since such stones may require more than one ESWL procedure or a more protracted percutaneous procedure (or the two in combination). The one clear conclusion that can be drawn is that open surgery is usually more expensive than less invasive technologies, and for simple stones its use is difficult to justify when alternatives are available. The relative cost advantages of ESWL over other technologies, of course, depend on the extent of use of the facility and, thus, the per-case costs of ESWL treatment.

A factor that should increase the cost advantage of ESWL over other technologies is the significant movement toward ambulatory ESWL, as evidenced by the three free-standing centers treating most of their patients on this basis (86). When overnight stays are eliminated, the cost of ESWL and related services may decrease by several hundred dollars per patient. These differences may be more apparent in hospitals offering both inpatient and outpatient ESWL than between hospitals and free-standing ESWL centers. Charges for ambulatory treatment at free-standing centers are not necessarily lower than charges for inpatient ESWL, perhaps due to higher construction costs for free-standing centers than for hospital-based units. For example, the free-standing center in California charges significantly more for ambulatory ESWL patients than the Methodist Hospital of Indianapolis does for ESWL inpatients ($7,200 vs. $5,698, physician charges included).

Percutaneous lithotripsy has now been performed on a few ambulatory patients with small stones (130). To the extent that percutaneous lithotripsy and ESWL can both be performed on ambulatory patients or on patients with very short hospital stays, the facility-based part of their costs may be similar. At present it appears that the applications of ambulatory percutaneous lithotripsy are much more limited than those of ambulatory ESWL.

DISABILITY COSTS

The short disability time away from normal activity that is associated with ESWL treatment is a significant advance over that accompanying open surgery, and it is probably shorter, on average, than the disability time associated with percutaneous lithotripsy. As of mid-1985, ESWL usually required patients to undergo 3 to 4 days of hospitalization associated with the treatment in most centers and under a week more of recuperation at home (3,11,137). Total disability time, including hospitalization and recuperation, as short as 7 days was reported even during the investigational phase of ESWL (187). The trend toward ambulatory ESWL implies that such experiences may now be closer to the norm than the exception. By comparison, a recent study in one hospital found that patients with simple small stones receiving percutaneous lithotripsy were hospitalized for an average of 4 days and returned to work an average of 6 days after hospital discharge, for a total disability time of 10 days. Similar patients undergoing open surgery for stones were hospitalized an average of 10 days and did not return to work for an average of 24 days after discharge (129).

It has been suggested that the advantages of ESWL are particularly great for persons in certain occupations in which the very presence of a urinary stone precludes normal work (115). Military pilots, for example, are not permitted to fly if they harbor stones, even asymptomatic ones, and some pilots have been known to request stone surgery in order to be able to pass future flight physical examinations (84,115). Thus, workers and employers (in this example, the Defense Department) may recognize substantial savings from ESWL over open surgery, and probably over percutaneous lithotripsy as well if current trends toward ambulatory ESWL continue.

Because disability time is very costly to both patients and employers, it may be a significant factor in determining patient demand for a particular treatment technology. Anecdotal evidence suggests that the short recuperation time associated with ESWL, the avoidance of an incision, and the expectation of less associated pain combine to encourage patients to choose ESWL over more invasive treatments when a choice is offered (28).

Chapter 6

ESWL and Federal Payment Policies

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INTRODUCTION

Third-party payment for health care services exerts a critical influence on the development, adoption, and use of medical technologies. Decisions to pay for the use of particular new technologies are explicit statements that those technologies are no longer considered investigational; decisions to cease paying for old ones are statements about the appropriateness of their use given the current state of the art. In turn, the method of payment for the use of technologies and the level of payment allowed can have a substantial impact, both on decisions by health care providers to acquire and use new technologies and on decisions by manufacturers to develop them.

Payment for medical technologies is more than a financial acknowledgment of services rendered. Because payment influences use, payment policies are a tool that can be used by government and private sector third-party payers alike in an attempt to influence use and encourage appropriate decisions about how to treat any given condition. The fact that payment policies do not always have these effects by no means diminishes the importance of this tool. Unintended and unavoidable consequences of a payment policy, as well as intended effects, affect the speed and extent of technology diffusion throughout the health care system and the way in which a technology is used.

The potential to treat many urinary stones less expensively with extracorporeal shock wave lithotripsy (ESWL) than with alternative technologies, despite the substantial price of ESWL equipment, makes this technology an easily identified target for payment policies that encourage providers to supply an adequate, but not excessive, amount of the service. In this chapter, it will become evident that payers have found this objective a particularly difficult one to reach. Payment for ESWL is strongly influenced by the fact that ESWL may be substituted for more expensive surgical procedures. There is strong pressure by providers to have those paying for ESWL do so at the same level as these more highly priced alternatives. From the payers' perspective, generous payment levels can encourage rapid diffusion of an innovative technology but are unlikely to control health care expenditures. Even more critically, high payment for ESWL may encourage overpurchase. Since the per-case technical cost of ESWL is so sensitive to the number of patients treated,[1] overpurchase would drive up the cost to ESWL centers of providing the technology.

Private and public sector payers alike moved quickly to include ESWL as a covered benefit once it was approved by the Food and Drug Administration (FDA) for marketing. The first plan to cover ESWL was Blue Cross/Blue Shield of Massachusetts, which initiated coverage only a few months after the procedure was first offered, in its investigational phase, at Massachussets General Hospital in Boston. Rather than waiting for the formal announcement by FDA that the Dornier lithotripter was approved for marketing, Blue Cross/Blue Shield of Massachusetts based its decision in part on the FDA's Advisory Panel on Urological Devices' recommendation for approval, which was announced at the end of May 1984. The insurance plan began covering the procedure in June 1984. At least one other Blue Cross/Blue Shield plan began covering ESWL before FDA approval was officially announced as well (155).

This chapter describes Medicare payment policies, how they apply to ESWL, and how they may influence the adoption and use of this technology. Since Medicare is both a significant proportion of the medical care market and a model for other purchasers, its influences can be pervasive. Hospital payment policies affect purchase and availability of ESWL equipment; payment for ambulatory services influence the site of care as well as the decision to purchase; and physician payment policies can influence physicians' willingness to perform the procedure.

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[1] Strictly speaking, the cost of an ESWL procedure declines with the number of procedures, not the number of patients (since a patient may have more than one procedure). However, relatively few patients undergo multiple ESWL procedures in one hospital stay, so the generalization that per-case costs decline as the number of patients increases is also true.

Three other Federal organizations provide or purchase health care for a significant number of Americans: the Veterans Administration (VA), the Department of Defense (DOD), and the Indian Health Service (IHS). The services provided or purchased by these organizations may also have a significant cumulative effect on the market for ESWL. This chapter concludes by reviewing the policies of these organizations for purchasing ESWL devices or services.

MEDICARE

Medicare payment policies affect the cost, distribution, and use of ESWL in four ways: through the decision to cover (or not cover) the technology, through the payment method, through the payment level, and through the fact that Medicare policies are a potential model for other payers. Hospital, ambulatory facility, and physician payment policies all may influence ESWL.

ESWL has important implications for Medicare, because it may often be the preferred treatment for some patients who are particularly likely to be covered by Medicare. Many elderly patients who form stones may have had previous operations for stones. Additional surgery could endanger their kidneys, and they are often at higher risk of complications from surgery than younger stone patients. Also, many disabled spinal cord injury patients are covered by Medicare. This population tends to form urinary stones repeatedly, and ESWL may prevent the need for multiple surgeries that could damage the kidneys. A final implication of ESWL for Medicare is that to the extent that ESWL can prevent kidney destruction through neglected stones or repeated operations, this technology can reduce the size of the population with end-stage renal disease, whose treatment is covered by Medicare. The latter benefit assumes, of course, that no damage from ESWL itself will develop over time.

Coverage Decisions

Medicare, enacted as a Social Security benefit in 1965, now provides medical care coverage for over 30 million aged and disabled persons (190). The Medicare program is prohibited by law from paying for medical services that are not "reasonable and necessary" (Public Law 89-97). This clause has been interpreted by the Health Care Financing Administration (HCFA) as precluding payment for experimental technologies. Decisions regarding when a new technology ceases to be experimental are largely left up to local intermediaries and carriers, the entities under contract to HCFA to make payments to beneficiaries on Medicare's behalf for hospital (Part A) and physician (Part B) services, respectively (178). These decisions can vary considerably across regions. One carrier may determine that a particular technology is safe and effective, for example, while another considers it still investigational and will not reimburse physicians for its use.

If payment for the use of a particular technology is sufficiently problematic, HCFA may request that the Public Health Service's Office of Health Techology Assessment (OHTA)[2] assess the status of the technology and make a coverage recommendation to HCFA. HCFA, in turn, will make a coverage decision based on that assessment and inform the carriers and intermediaries of the decision. Until recently, cost criteria were not included as factors in assessments for Medicare coverage decisions, and expensive technologies were eligible for coverage without regard to cost effectiveness (178). However, Public Law 98-551 expanded OHTA's medical technology assessment criteria to allow examination of cost effectiveness and medical appropriateness issues as well (181).

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[2] OHTA has no organizational affiliation with the Congressional Office of Technology Assessment. OHTA evaluates medical technologies for the Health Care Financing Administration for the purpose of making coverage decisions under Medicare and Medicaid.

HCFA's criteria for determining whether a technology is experimental for purposes of Medicare reimbursement differs in an important way from FDA's criteria for determining whether a technology should receive premarket approval. FDA considers a medical device to be safe and effective when, on the basis of valid scientific evidence, the device is shown to be safe and to have the effect claimed by the manufacturers under the manufacturer's specified conditions of use (21 U.S.C. 260). On the other hand, HCFA's criteria include consideration of the state of development of the technology, the degree of acceptance of the technology in the medical community, and the likelihood that the technology will produce a health benefit (176). Thus, a technology may be approved by FDA for marketing purposes but not covered by HCFA for payment (178).

In the case of ESWL, cost considerations probably helped to prompt the Secretary of the Department of Health and Human Services' request for an expedited coverage review of this technology (186). HCFA announced in May 1985 that Medicare would cover ESWL beginning with any treatments administered on or after March 15, 1985 (12), only 3 months after FDA approved the Dornier lithotripter for marketing and 11 months after the first ESWL device was installed in the United States. In contrast, HCFA first approved coverage of computed tomography (CT) scanning, an expensive diagnostic technology, 39 months after the first U.S. scanner was installed (169). Magnetic resonance imaging (MRI), a complex as well as a costly diagnostic technology, did not receive formal coverage under Medicare until November 1985 (191), nearly 60 months after MRI first appeared in the United States (169). These technologies are not directly comparable to ESWL, since they are diagnostic rather than therapeutic technologies and have a more complex set of potential uses. Still, the contrast demonstrates that ESWL underwent a relatively quick and efficient coverage process. The primary difficulty that ESWL presented to Medicare coverage concerned not the medical abilities of this technology but ESWL's classification for payment purposes, discussed in the next section.

Hospital Payment

Classification of ESWL

Services received by a Medicare beneficiary as a hospital inpatient are covered under Medicare Part A and paid through Medicare's prospective payment system (PPS). Under PPS, hospitals are reimbursed at a pre-set rate for each Medicare patient they admit for diagnosis or treatment. Capital costs (depreciation, interest, and return-on-equity to for-profit institutions) and costs associated with medical education are not included in the rates,[3] and PPS does not presently apply to Part B services, such as physician visits and hospital outpatient services.

The payment rate itself depends in most cases on four elements:

1. the patient's principal diagnosis,
2. the principal procedure performed on that patient,
3. the patient's age, and
4. the presence or absence of any medical complications or coexisting diseases.

Based on these elements, each hospital patient is assigned to a diagnosis-related group (DRG). A person with a principal diagnosis of urinary stones who required treatment might be classified into any of six DRGs, as listed in table 11. The payment received by the hospital for treating that patient depends on the weight[4] of that patient's DRG; weights are greater (and payment higher) if the patient is over 69 years of age, has coexisting conditions needing treatment, or undergoes a surgical rather than a medical procedure.

A major dilemma that surrounded Medicare coverage of ESWL for hospital payment purposes concerned how the use of this technology should be coded under the International Classification of

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[3] As of December 1985.

[4] DRG weights are based on the relative operating costs of treatment for the average patient within each DRG. A patient in a DRG with a weight of 2.0, for instance, is assumed to require on average four times the resources of a patient in a DRG with a weight of 0.5. Corresponding to these weights, Medicare DRG reimbursement to the hospital for the first patient would be roughly four times as high as reimbursement for the second. Actual payments depend at present on actual hospital costs and other factors.

Table 11.—Diagnosis-Related Groups Used as Basis for Medicare Payment for Urinary Stone Treatment, 1986

Diagnosis-related group			Weight[a]	Arithmetic mean length of stay (days)[b]
304	(surgical)	major urinary procedures, age 70 or older or with comorbidities and complications	2.0323	13.5
305	(surgical)	major urinary procedures, under age 70 without comorbidities and complications	1.4894	10.4
310	(surgical)	transurethral procedures, age 70 or older or with comorbidities and complications	0.7266	5.6
311	(surgical)	transurethral procedures, under age 70 without comorbidities and complications	0.5563	4.1
323	(medical)	urinary stones, age 70 or older or with comorbidities and complications	0.5863	5.1
324	(medical)	urinary stones, under age 70 without comorbidities and complications	0.4098	3.6

[a] The weight assigned a DRG is assumed to represent the relative costliness of resources used for patients in that DRG. Payment for a DRG with a weight of 2 is approximately four times that for a DRG with a weight of 0.5

[b] The average length of hospital stay for patients in that DRG.

SOURCE: 50 FR 35646.

Diseases, Ninth Revision Clinical Modification (ICD-9-CM), described in appendix C. Each diagnosis and each procedure has a corresponding code that is used to represent that diagnosis or procedure on the hospital's patient discharge sheet. These codes in turn are used by the DRG Grouper—the computer program used by Medicare intermediaries (and many hospitals) to assign DRGs—to determine which DRG is the applicable one for that patient.

The problem of classifying ESWL for hospital payment purposes involves not the diagnostic codes but the procedural ones. Since ESWL is a new technology, there is no ICD-9-CM procedure code specifically intended to correspond to its use. Surgical removal was the usual nonmedical treatment for urinary stones when the coding system was last revised. The only code that specifies stone fragmentation is the code for ultrasonic lithotripsy (59.95), which is usually reported together with a second code that represents the endoscopic procedure for which ultrasonic lithotripsy is used (see app. C). ESWL has been temporarily assigned this ultrasonic lithotripsy code (50 FR 24374). When used alone, without an accompanying code for an invasive procedure (as is the case for simple ESWL treatment), this code causes ESWL to be classified for PPS purposes as medical treatment (126).

Level of Payment for ESWL

Because ESWL is classified as "medical" rather than "surgical," the procedure is reimbursed at a level that is only about one-third of that for surgery or percutaneous lithotripsy, the main alternatives (see table 11). This occurs because the weights assigned to DRGs 304 and 305 for surgical treatment of kidney stones—and thus the payment to the hospital for those DRGs—are triple the weights for medical treatment. Since treatment by ESWL alone places a patient in one of these medical DRGs (323 or 324), use of it without an adjunct procedure brings the hospital roughly one-third the payment that it would were the procedure assigned into DRGs 304 or 305.[5]

Under PPS, the incentive or disincentive for hospitals to encourage physicians to prescribe ESWL depends not only on how much ESWL is reimbursed relative to invasive procedures but also on how its per-case operating costs compare to the DRG payment to the hospital. From the point of view of operating costs, ESWL will be favored by hospitals if the surplus of DRG payment over costs is larger (or the deficit smaller) than the difference between payment and cost for alternative procedures, regardless of the DRG in which the alternatives are classified. Since different hospitals will have different costs for each alternative, including ESWL, the direction and size of financial incentives will vary as well.

As an example of how a hospital might fare when providing ESWL to Medicare patients, one can calculate a very rough average payment rate for DRG 323. If the phase-in period for PPS had been complete, and a hospital's DRG payment had not been partially dependent on that hospital's actual costs, the 1984 Federal standardized

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[5] The creation of a new ICD-9-CM code and a new DRG for ESWL has been suggested as a long-run solution to this classification problem (50 FR 24374).

DRG payment (exclusive of regional adjustments for wage rates, etc.) for operating costs in DRG 323 would have ranged from approximately $1,400 in rural regions to approximately $1,775 in urban ones.[6] DRG 324 has a lower weight than DRG 323 and correspondingly pays a lower amount (in this simplified calculation, $979 to $1,227, depending on hospital location). Based on these figures, it would appear that as long as ESWL is classified as a medical procedure under PPS, and the weights of DRGs 323 and 324 remain unchanged, some efficient urban hospitals—those with low per-case ESWL costs and minimal ancillary costs and lengths of stay for uncomplicated patients—may be able to perform the procedure within the payment rate even when PPS is fully implemented. For example, the hypothetical hospital in table 5 treating 1,500 patient per year would have average per-case operating costs of $1,638 for patients with 4-day stays. However, these assumed Federal DRG rates are approximate, and even some efficient hospitals might have losses.

The Prospective Payment Assessment Commission (ProPAC), which offers recommendations to HCFA regarding PPS, examined actual average 1984 DRG payments for ESWL in seven hospitals (131). ProPAC found average payments of $2,655 for DRG 323 and average payments of $1,857 for DRG 324. Based on reported average costs of these hospitals (see table 5, ch. 5), ProPAC estimated that the DRG payments covered these hospitals' costs 98 percent of the time in DRG 323, but only 68 percent of the time in DRG 324. The Commission compared its estimates with information from a survey of 16 hospitals with ESWL centers. These hospitals received average payments $2,557 for DRG 322 and $1,787 for DRG 324 (40). This preliminary analysis led ProPAC to recommend that all ESWL admissions be temporarily classified into DRG 323 (131).

Overall effects of PPS on ESWL depend on reimbursement for the capital cost of acquiring the lithotripter as well as the operating costs of using it. In particular, the overall effects depend on whether or not capital costs continue to be treated as a pass-through.[7] Under the current provisions, hospitals acquiring the device are reimbursed for Medicare's share of the actual costs of depreciation and interest. It is unlikely that this pass-through provision for capital costs will be extended past fiscal year 1987 (which ends October 1987), and the decision on precisely how Medicare's share of capital expenses will be paid in the future may have a substantial effect on hospitals' decisions to install ESWL units. Any difficulty in recovering the average costs of serving Medicare patients could be exacerbated if capital costs are incorporated into PPS.[8]

Hospital Strategies

As hospitals gain experience with ESWL, the per-case costs of ancillary and routine care services are likely to decline. Length of stay for ESWL, for example, already appears to be declining. However, if more hospitals continue to acquire ESWL units and the caseloads at each hospital declines accordingly, low per-case costs will be more difficult to realize. Unless payment rates rise, profits will also decline.

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[6] For simplicity's sake, these figures are calculated in 1984 dollars, and with 1986 DRG weights, but as if the prospective payment system's phase-in period were complete; they do not represent actual payments to any hospital. They also ignore area wage-related and other adjustments. Payment rate = DRG weight × standardized national payment amount (after urban/rural adjustment). The national rural rate is 0.5863 × $2,388.08 = $1,400.13; the national urban rate is 0.5863 × $2,993.45 = $1,775.06. For DRG 324, with a weight of 0.4098, the rates are $978.63 and $1,226.72, respectively. (Standardized dollar amounts are from *49 FR 27446*.)

[7] Capital costs include such factors as depreciation on plant and equipment and interest on loans for these acquisitions. Under current Medicare law, the proportion of these costs that apply to Medicare-related treatment are paid to the hospital as a "pass-through," i.e., reimbursed at actual cost rather than as a part of the per-case payment rates. Congress and the Department of Health and Human Services are currently considering a number of proposals to reimburse capital expenses, such as a flat percentage add-on to DRG payment amounts (73).

[8] The extent to which the inclusion of capital costs in PPS will affect hospitals' purchasing decisions regarding ESWL depends on whether hospitals consider the investment in terms of the income generated by the DRG payments for urinary stones, or whether they consider the investment in terms of total anticipated surplus from all DRG payments. If, for example, all DRG payments were increased by 7 percent to cover capital costs, hospital administrators under the first strategy might decide not to invest because the additional 7 percent of the rate for urinary stone treatment would be unlikely to cover the purchase price of the ESWL device. Administrators making decisions under the second strategy, on the other hand, might consider the investment if they had no other significant capital obligations that year, because the additional 7 percent of total PPS revenue would cover the price.

Nevertheless, there are a number of incentives to provide ESWL, and a number of strategies for providing it, that exist even if a hospital expects little or no profit (or surplus) from providing the service to Medicare patients. For example, a minimal profit from providing ESWL may be acceptable if it is dependable, with little variation in costs among patients treated. One advantage that ESWL (when performed alone) holds over all the invasive alternatives is the potential for fewer postprocedure complications (187). As a result, hospitals may be able to expect less variation in the length of stay and fewer outliers.[9]

Even if hospitals under PPS cannot recoup direct costs when treating Medicare patients with ESWL, they may still treat these patients in order to enhance their public image and attract other patients. Or, they may use ESWL if, once the lithotripter is acquired, treating Medicare patients enables the unit to be used to full capacity, lowering the per-case costs of all patients treated and thus enabling the hospital to produce a surplus from other payment sources.

Two other alternatives are available to hospitals that cannot recoup the costs of performing ESWL under present DRG payment. First, hospitals can treat patients as outpatients, whose care is currently reimbursed at cost rather than at a fixed rate. Second, the hospital could readmit patients who required a secondary procedure to ESWL (or a second ESWL treatment). In this case the hospital would be paid twice, and if the secondary procedure were percutaneous lithotripsy, the second payment would be at a higher rate, because percutaneous lithotripsy is classified into the more heavily weighted DRG that includes admissions for major urinary surgery (see table 11). In some cases the second admission might be at the patient's local hospital rather than at the ESWL center hospital, a situation that would provide a financial advantage to the local hospital, but not to the one providing ESWL.[10]

Impacts of ESWL on Medicare Inpatients

The past records of DRGs can give a rough maximum estimate of the Medicare population that might use ESWL, as well as some baseline comparisons for actual use (155). The Medpar database compiled by HCFA consists of a 20 percent sample of all Medicare admissions during 1981. It was the original source for developing and verifying the DRG methods currently used by Medicare to pay hospitals. Table 12 shows data derived from the Medpar database for admissions in 1981 in DRGs relating to stone disease.

The surgical DRGs for treatment of urinary tract disorders (304, 305, 310, 311) are relatively broadly defined and may include a number of cases beyond those that would ultimately receive ESWL. This situation occurs because these DRGs encompass other major ureter and kidney procedures as well as surgery for stones. Estimates derived from the Medpar data should, however, represent the upper limit of stone surgery (155).

DRGs 304 and 305 include major open surgery on the kidney. Together these DRGs, representing the group of Medicare patients who would be most affected by the use of lithotripsy, accounted for 25 percent of all surgery performed on the kidney in 1981. The second major group of Medicare patients who received surgery in 1981 were those who underwent a transuretheral procedure, classified into DRGs 310 and 311. These DRGs accounted for the remaining 75 percent of the cases that may have undergone a "surgical" procedure for stone removal. To the extent that ESWL now substitutes for these procedures, there will be fewer than in 1981. However, some patients who undergo ESWL may need an additional transuretheral procedure to remove small fragments that do not pass spontaneously. Therefore,

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[9] Under Medicare's PPS, an "outlier" is a patient whose associated costs or length of stay greatly exceeds the mean for the relevant DRG.

[10] A third possibility is that hospitals might admit patients for care after they have received ESWL elsewhere, or even on an ambulatory basis in the same hospital. This option is discussed in the next section on ambulatory ESWL.

Table 12.—Medicare Admissions in DRGs Relating to Stone Disease as Represented in the Medpar Database, 1981[a]

Treatment	DRG	Admissions	Mean hospital charge	DRG weight	Mean length of stay (days)
Surgical and transurethral procedures	304	1,725	$5,077	1.7952	12.8
	305	1,039	3,708	1.7043	11.9
	310	6,162	1,534	0.7071	4.9
	311	1,779	1,277	0.5871	4.1
Total		10,705			
Medical treatment for urinary stones	323	6,691	1,551	0.7131	4.9
	324	3,165	1,180	0.5472	3.9
Total		9,856			
Urinary tract signs and symptoms	325	6,799	1,577	0.7247	5.4
	326	2,020	1,274	0.5875	4.3
	327[b]	0	0	0.5027	3.1
Total		8,819			

[a] The Medpar database in 1981 contained a 20-percent sample of Medicare hospital bills. It is maintained by the Health Care Financing Administration and is the source from which DRG weights and mean lengths of stay were calculated.

[b] This DRG represents treatment for urinary stone symptoms for children aged 0-17. The Medpar database did not include cases in this group due to insufficient numbers. The Medicare data was supplemented by data from Maryland and Michigan to derive DRG weights and mean lengths of stay.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration data, as cited in J.A. Showstack, E.J. Perez-Stable, and E. Sawitz, "Extracorporeal Shock Wave Lithotripsy: Clinical Application and Medicare Physician Payment," paper prepared for the Office of Technology Assessment, Washington, DC, August 1, 1985.

the expected reduction in transuretheral procedures due to the introduction of ESWL may not be as great as the reduction in open procedures (155).

Medicare currently pays for ESWL as an inpatient procedure in DRGs 323 and 324, which are for the medical treatment of stones. Presumably these DRGs include patients who are admitted for supportive (fluid and analgesic) therapy until the stone is passed spontaneously. They may also include metabolic workups for stone disease. In 1981, there were almost as many Medicare admissions in these DRGs (8,856) as there were total surgeries in DRG 304, 305, 310, and 311 (10,705) (155). As currently used, ESWL has only a small role in the acute care of patients with stones, and it is unclear how substantially this large pool of stone disease will be affected by ESWL. It can be argued that as ESWL becomes more common, the criteria for its use in the acute phase of stone disease will be less restrictive, and many of these patients may receive ESWL. Thus, there would be a shift from conservative medical treatment to more direct interventions (155).

The difficult problem faced by Medicare is to ensure access to ESWL without encouraging, through high payment rates, overpurchase of ESWL units and overuse of them once they are installed. Since overpurchase, which leads to higher per-case costs, and overuse, which implies unnecessary care, can both lead to higher Medicare expenditures than would occur under more prudent use, the problem is not a trivial one.

One strategy is for Medicare to pay for ESWL admissions at a rate very close to (or even lower than) average costs, a strategy with several potential effects. First, Medicare total payment rates (including payments for capital expenses) that are lower than average costs[11] may discourage purchase of a Dornier lithotripter in some instances, if potential purchasers anticipate that Medicare patients will be a significant proportion of the lithotripter caseload. To the extent that this disincentive restrains all but a few hospitals in any region from installing ESWL units, the low payment rates will themselves help ensure that per-case costs stay low because the machines that exist can be used to capacity. Low Medicare payment rates may also discourage unnecessary ESWL procedures where patients can be treated more appropriately with safer or less expensive therapies. Thus, low payment rates may reduce Medicare expenditures still further while actually enhancing the quality of care provided to those individuals who might have undergone unnecessary procedures. However, to the extent that all patients must travel further and wait longer for ESWL due to fewer devices, low Medicare payment rates will reduce access to ESWL.

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[11] Average costs = total costs ÷ number of patients served. Average costs decline as the number of ESWL patients increases, but at high numbers they may decline very slowly. They are contrasted with marginal costs, which are the additional costs incurred from treating one more patient. For ESWL, marginal costs include the cost of that patient's anesthesia, electrodes, electricity, other supplies, laboratory and radiologic tests, and patient care. They do not include the cost of the machine itself, which has already been incurred and remains even if no patients at all are treated. Within the caseloads for which ESWL has been used to date, average costs have probably been higher than marginal costs.

Another effect of low Medicare payment rates may be to reduce access to ESWL specifically for Medicare patients. Some centers may be willing to treat Medicare patients as long as payments cover the marginal costs of ESWL treatment (i.e., the costs of actually using the machine on that patient, such as staff time, supplies, hospital bed, and ancillary tests, but not including capital costs). Facilities that cannot recover even these marginal costs of treating Medicare patients will have strong incentives not to treat such patients if alternatives are available. For example, a hospital might encourage physicians to provide alternative (and possibly less safe) treatments to these patients, if alternatives existed with costs that were lower than the respective reimbursement rates for those therapies. Or, the facility could encourage physicians to refer Medicare patients to another ESWL unit. Since few ESWL treatments are done to resolve immediately life-threatening complications, the latter is an entirely plausible scenario; some patients might be given a choice between a long wait for treatment at that facility or a referral to an ESWL unit in another facility, another city, or even another State.

If hospitals can recover the marginal but not the average costs of treating Medicare patients, then all fixed costs (e.g., interest, depreciation, maintenance contract) must be borne by other payers of patients receiving ESWL. As chapter 5 demonstrated, the charges of most hospitals currently providing ESWL are probably considerably higher than their costs. Individuals or third-party payers that reimburse for services on the basis of charges would bear most of the fixed costs of the ESWL units in this scenario.

An issue currently faced by Medicare is whether to change the DRG payment level for ESWL. Three methods of changing payment have been proposed. First, payment for ESWL could be changed by recalculating the costs of the two DRGs in which it is currently classified ("recalibration"). The effect of this strategy would be to pay for patients who receive ESWL at a rate close to average costs and to pay for patients in those DRGs who receive other therapies at a rate higher than average costs. This strategy would probably have little effect on the incentives of hospitals to encourage physicians to treat patients with ESWL rather than surgery. A second option would be to reclassify ESWL into the DRG that includes open and percutaneous surgery for stones. This alternative would offer hospital administrators a direct incentive to encourage physicians to offer the least costly of the three procedures. However, it could also increase expenditures of the Medicare program by offering an incentive to perform ESWL on patients who would not otherwise be considered for aggressive treatment. A third alternative is to create a new DRG exclusively for ESWL. This option would most accurately reimburse actual average costs, but it would not necessarily discourage hospitals from overpurchasing. It also set a precedent for gallstone lithotripsy, which may soon face similar issues.

Finally, a fourth option that has not been proposed publicly would be the inclusion of ESWL procedures in DRGs 310 and 311, the DRGs for transurethral procedures. These DRGs have weights slightly higher than DRGs for medical treatment but considerably lower than those for open surgery.

Payment to Ambulatory Facilities

Because of its noninvasive nature, ESWL probably can be used safely on an ambulatory basis under controlled circumstances for selected patients, where the patient is available to a urologist for pre- and postprocedure observation and testing and where appropriate hospital facilities are readily available for any postprocedure complications. As yet, ambulatory services, including hospital outpatient services, are not incorporated into PPS.

Ambulatory services are reimbursed by Medicare under Part B, the Supplementary Medical Insurance program. Unlike Part A, Part B requires the beneficiary to pay monthly premiums, an annual deductible, and 20-percent coinsurance for many (but not all) services. The services provided by physicians, or in physicians' offices, are paid separately from the services provided in other facilities and are discussed in the next section. This section describes payment to other ambulatory facilities, namely hospital outpatient departments and ambulatory surgical centers (ASCs), which can receive direct Medicare payments to cover the costs of the facility, nursing and other staff services, routine supplies, and equipment.

Services provided in a hospital outpatient department are currently reimbursed by Medicare on the basis of the actual cost of providing them, unless the outpatient department has been separately certified as an ASC. Hospital outpatient services are not limited to any specific set of procedures.

By contrast, ambulatory services provided in a Medicare-certified ASC facility, either hospital-based or free-standing, are reimbursed according to a fee schedule. Only procedures specifically approved by HCFA for provision in an ASC are reimbursable under Medicare in this setting. Each procedure is classified into one of four rate categories, depending on the complexity of the service. An ASC is reimbursed at the appropriate full rate for the primary procedure performed and at 50 percent of the appropriate rate for secondary procedures. ESWL has not yet been included as a reimbursable procedure when performed in ASCs (189).

The HCFA coverage decision for ESWL did not explicitly restrict payment to inpatient ESWL treatment, so hospital outpatient ESWL is reimbursable under Medicare (205). The financial incentives under Medicare for hospitals to provide ESWL to ambulatory patients rather than inpatients will depend on: 1) whether the DRG-based payment is higher than marginal hospital costs, encouraging hospitals to increase hospital admissions for lithotripsy; 2) whether hospital outpatient services become incorporated into PPS; and 3) whether a significant proportion of ambulatory patients receiving lithotripsy subsequently require hospital admission for postprocedure complications.

Medicare's policy is not to pay for hospital outpatient services if the patient was admitted to the hospital immediately afterwards (48 FR 250), though this policy may be very difficult to enforce. If a patient is given ambulatory lithotripsy treatment but must be admitted as an inpatient afterwards due to complications or a need for observation, the hospital should, according to regulations, be reimbursed only for the inpatient stay; the costs of the outpatient ESWL treatment would be disallowed. However, as long as ESWL treatment is classified into a medical DRG, the hospital has little to lose by trying outpatient treatment first because an admission after ESWL treatment could still legitimately be classified as medical treatment for urinary stones and thus would be reimbursed at the same rate as an admission that included ESWL treatment. Unless the preprocedure treatment was detected and payment for either the admission or the ambulatory procedure was denied, the hospital would receive payment not only for the costs of outpatient ESWL, but also payment for the post-ESWL admission at the same rate as if that admission had included ESWL treatment.

The incentive for an ASC to offer ESWL to Medicare patients depends, first, on whether Medicare approves the procedure as reimbursable if performed in that setting; and, second, on the size of the fee paid for free-standing center treatment relative to the cost of providing it. At present the standard maximum payment for a single ASC procedure, before labor index adjustments, is $336 (189). An ASC must accept that amount as payment in full for all but the professional components of the service. If HCFA, in the future, were to include ESWL as a reimbursable ASC procedure, the agency could also create a new rate category for it. Without a higher rate category, there would be little incentive for ASCs to offer ESWL to Medicare patients. Nonetheless, the first ESWL treatment center in northern California, a nonhospital free-standing facility, has obtained Medicare certification as an ASC and has treated Medicare patients (68). As yet, since ESWL is not on the list of approved procedures for ASCs, this facility cannot receive payment from Medicare. Thus, in facilities such as this one, Medicare patients must pay the full facility-related charges themselves unless they have private insurance that covers the service.

The settings in which ESWL is provided may be strongly affected by different payment methods and payment levels. At present, because ESWL is not reimbursed by Medicare when provided in ASCs, only hospitals can receive direct payments for the facility-related portion of the costs of providing ESWL. If hospital outpatient services continue to be reimbursed on the basis of cost, any hospital in which the DRG payment is lower than cost will have a financial incentive to provide ESWL to Medicare patients as outpatients rather than as inpatients.

The Medicare patients currently undergoing ESWL in ASCs are incurring very high out-of-pocket expenses, unless they have supplementary insurance that covers the treatment in this setting. These patients, as well as the ASC providers, may try to influence HCFA to provide Medicare coverage for ESWL in this setting. If HCFA should do so, it would probably also need to establish a new rate category. The current rates were originally based on average charges for procedures in each category, but the rates have not been increased since they were established in 1982. It would probably be financially imprudent for any ASC to provide ESWL to Medicare patients at present rates.

Payment for Physician Services

Physician services to Medicare patients, regardless of the setting in which they are provided, are reimbursed under Part B. The amounts paid to physicians for their services are not determined either on the basis of cost or by a nationally based rate schedule. Instead, payment amounts are calculated by the carriers (the Part B Medicare contractors) in each region of the United States and are based on physician charge data in that area.

Medicare pays physicians for their services on the basis of the approved charge per service. This approved charge, except in special circumstances, is defined to be the lower of the actual charge billed by the physician, the physician's customary charge for that service, and the prevailing charge of physicians in the area for that service.[12] (This method is commonly referred to as "CPR" payment.) Medicare then pays for 80 percent of the approved charge, less any deductible owed by the patient. The patient pays the remaining 20 percent. In addition, if the physician does not accept the Medicare-approved charge as full payment ("accepting assignment"), the patient is liable for any charges in excess of the approved amount.

Since ESWL is a new technology, each carrier must determine the approved charge for the procedure without any historical Medicare data. Because ESWL is currently performed by urologists and partially replaces percutaneous and open surgical methods of upper urinary stone removal, the prices paid by Medicare for these procedures have formed the early basis for determination of payment for ESWL. Table 13 presents some sample urologists' fees for various stone removal proce-

Table 13.—Sample Urologists' Fees for Selected Stone Removal Procedures, 1985[a]

Procedure	Fee
Nephrolithotomy for staghorn stone	$2,500
Simple nephrolithotomy	1,500
Pyelolithotomy	1,500
Ureterolithotomy	1,500
Percutaneous nephrostolithotomy	2,000
Ureteroscopy and stone removal	1,250

[a] See glossary (app. D) for definitions of procedure terms.

SOURCE: American Urological Association, "Summary and Recommendations of the Ad Hoc Committee To Study the Safety and Clinical Effectiveness of the Current Technology of: 1) Percutaneous Lithotripsy, and 2) Non-Invasive Lithotripsy," presented to the AUA, New Orleans, Louisiana, May 9, 1985.

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[12] "The customary charge is the physician's median submitted charge for that service during the data collection period preceding the fee screen year. The customary charge is fluid. If a physician revises his or her fees, the carrier will recognize the change when processing claims with the new charges" (182). The prevailing charge is the lowest charge that is greater than or equal to the 75th percentile of the distribution of all physicians' customary charges weighted by the number of times each physician billed for the service in that locality during the calendar year preceding the fee screen year. Since 1972, the prevailing charge is limited in its rate of increase over time by the Medicare Economic Index, an annually adjusted index that relates the increase of physicians' fees relative to increases in costs and general earnings levels (182).

dures. The price paid by Medicare varies in each region both because the contemporary charges for stone surgery vary in each region and because each carrier establishes rates independently in various ways.

Massachussetts Blue Cross/Blue Shield, for example, the carrier for Medicare in that State, established physician payment for ESWL at a rate roughly equal to pyelolithotomy[13] plus urography, or approximately $1,250 per procedure (155). Blue Cross/Blue Shield of Virginia, based on negotiations with the one urologist-owned facility that performed ESWL in that State as of 1985, agreed to reimburse physicians approximately $1,200 for the procedure, about the same level as a percutaneous removal of a stone in the upper ureter. Blue Shield of Greater New York reported that it had established a negotiated fee "substantially less than the usual pyelolithotomy fee of approximately $1,900" (155). Blue Cross/Blue Shield of Texas considered ESWL a routine "surgical" procedure and decided on a level of reimbursement based on a surgeon's time involved in monitoring the procedure. A reimbursement level was established at a rate "somewhat less than $2,000" (155). For many payers, the incentive to offer a fee lower than that for surgical treatment has been tempered by the desire to maintain a nonadversarial relationship with both patients and physicians (155).[14]

Many Medicare carriers still have little experience in paying for ESWL; carriers in States that do not yet have lithotripters may have no established policy for payment for the procedure. In January 1986, HCFA issued guidelines to help carriers develop a "reasonable" charge for the service. In these guidelines, HCFA suggested that physicians might be appropriately reimbursed for ESWL at a rate comparable to that paid for radiological procedures rather than at a rate comparable to that for surgery (192). Although these guidelines are not binding on the carriers, they help carriers justify paying physicians less for ESWL than for urinary stone surgery.

Policy is also lacking in an area relating to the provision of ambulatory ESWL: physician reimbursement for a technical fee. Medicare regulations specify that it will pay for physician services and for supplies "incident to" those services that are common office supplies and included in the physician's bill (42 CFR 405). Because certain "incidental" services provided by office physicians (such as radiologists) have substantial equipment costs, these services are paid by Medicare in two parts: one part for the professional fee (e.g., for interpreting an X-ray), and one part for the "technical" fee (e.g., for use of the X-ray equipment). In essence, the technical fee is the equivalent of a facility fee for physicians who own and operate major medical equipment in their offices. ESWL is neither a "common" office supply nor "incidental" to the patient's treatment, and HCFA's current policy is that no technical fee can be paid to physicians who own as well as operate ESWL equipment (72). However, if ESWL is commonly provided in nonhospital settings, and it is not a reimbursable ASC procedure, some changes in this policy may be indicated.

A more general problem with the current method used by Medicare to pay physicians is that it does not adjust prices paid for performing new procedures as the costs of those procedures decline over time. In the short run, while physicians are learning ESWL, it may be appropriate to pay for the procedure at the same rate as percutaneous or open surgery. Over time, however, as physicians become more experienced and make more efficient use of their own time and the support staff, and as the technology itself evolves, the costs of performing ESWL will fall. Under the current system, however, the prices paid by Medicare are likely to remain high, because they will be based on the ample charges of the past. This pattern has been noted with coronary bypass surgery, in which the initially high charges for the procedure remained even after the costs of performing it had declined dramatically (140).

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[13] Pyelolithotomy refers to open surgery for stones in the renal pelvis.

[14] It is interesting that ESWL is categorized as "medical" for Medicare hospital payment purposes but is categorized as "surgical" for physician payment purposes. Arguments over whether or not ESWL is a "surgical" procedure (and, by implication, should be performed only by surgeons) are frequently heated and illuminate the novel characteristics of this technology (see ch. 5).

A number of alternative ways to pay physicians are currently under consideration, and the method chosen could have some effect on the provision of ESWL to Medicare patients (182). Figure 2 presents a schematic representation of how these alternatives, discussed below, relate to the services provided a urinary stone patient.

The least drastic change would involve some adjustment to the present payment system, retaining the current method of deriving an approved charge but eliminating differences in payment among physicians in different specialties or regions providing the same service. Eliminating specialty differentials would be likely to have little effect on ESWL, at least in the short run, since at present only urologists perform the procedure. Eliminating geographic differentials would only be likely to have an effect if one price were paid across all States; prices within States are likely to be similar anyway due to the relatively small number of lithotripsy centers. As is apparent from the previous discussion, if differences across States were eliminated, some urologists might be paid several hundred dollars more or less than at present. A third potential adjustment to the present system would be to reevaluate expensive new procedures, such as ESWL, after they have been in use for a short time and lower the approved charge if the assessment indicated that the physician costs of providing those procedures had declined. For example, carriers might explicitly reevaluate the relative time required by physician for ESWL in 2 or 3 years to determine whether the payment rate should be adjusted.

Taking a somewhat different approach in the context of the current system, Medicare might contract with one or more physicians and lithotripsy centers in each area who are willing to provide the service at a lower price than their competitors. The contracting option may be attractive for Medicare in regions where several lithotripters exist, although it is not without drawbacks. On the one hand, Medicare holds a small but substantial market share of the demand for this technology,[15] and most physicians would probably dislike losing their entire Medicare business. On the other hand, if physicians at only certain ESWL facilities would perform ESWL for the Medicare price, beneficiaries would either have to use those facilities (possibly traveling long distances to do so) or be liable for large uncovered amounts.

Another option for paying physicians is to use fee schedules, in which each service is reimbursed at a set fee that does not depend on actual charges (although the initial schedule could be based on charges). This option might enable Medicare to adjust the price of ESWL more easily over time, either based on an analysis of resource costs or a comparison of relative charges for ESWL and alternative technologies. Some fee schedule approaches, however, might require intense negotiations over the relative value of performing ESWL, similar to current determinations of the starting "reasonable" rate for performing the procedure.

A third option being considered is payment for packages of related services. These packages could take a number of forms. For example, Medicare could pay for all the inpatient physician services provided to a patient at a single rate that depended on the DRG of that patient. Or, Medicare could package physician services provided in any setting into some classification system analogous to DRGs and reimburse at a set rate for each package. The first alternative might tend to encourage outpatient ESWL, while the second might encourage the least costly setting for providing ESWL. Other alternatives, such as paying a set rate for all services provided in conjunction with a particular procedure, could influence the mix of physicians involved in ESWL and the incentives to provide ESWL rather than alternative modes of treatment. However, there is no experience with payment for packages that include the services of more than one physician, and for some alternatives no usable payment categories have been developed (182).

A final option, capitation payment, involves paying a provider or some intermediary a set rate per beneficiary for all the covered care used by that person during the year (or some other time period). An important feature of capitation is that it would encourage provision of the least costly

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[15] The actual number of people with upper urinary stones who are eligible for Medicare is unknown, but these patients probably represent somewhat less than a quarter of the total population with such stones (205).

Figure 2.—Alternative Methods for Medicare Payment for Services Provided to a Hypothetical Patient Presenting the Symptom of Extreme Flank Pain[a]

Pre-hospital ambulatory services					Inpatient services									Post-hospital ambulatory services				
First office visit: primary physician	First office visit: urologist	Urinalysis	Intravenous pyelogram (IVP)[b]	Radiologist service for IVP	Radiologist service for KUB X-ray[c]	Anesthesiologist service for extracorporeal shock wave lithotripsy (ESWL)	Urologist services: ESWL and hospital visits[d]	Physician consultant services[f]	ESWL procedure	Hospital stay[g]	Urine culture	KUB X-ray	Blood tests	Post-hospital office visit: urologist	IVP or KUB X-ray	Radiologist service for IVP or KUB X-ray	Second post-hospital visit: urologist[h]	One office visit every 6 months: urologist
Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service[e]	Fee-for-service	DRG payment for inpatient facility services					Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service	Fee-for-service
Ambulatory-episode-of-care package					Inpatient-episode-of-care package for physicians' services				DRG payment for inpatient facility services					Ambulatory-episode-of-care package				Ambulatory visit package
Capitation payment[k]																		

▨ Payment by CPR or fee schedules[i] ■ Packaged payment[j]

[a] The actual treatment would depend on the particular patient. Some patients might be seen initially in an emergency room or require a procedure other than ESWL, such as surgery.

[b] An intravenous X-ray of the kidneys and ureters.

[c] X-ray of the kidneys, ureters, and bladder.

[d] The number of hospital visits would vary with the patient's length of stay.

[e] The urologist peforming ESWL might charge a fee for the ESWL procedure separate from fees for related hospital visits, or instead might charge a global fee covering both the procedure and the visit.

[f] Some complicated patients might need to be seen by specialists such as cardiologists.

[g] The current average length of stay for ESWL is 3.3 days (40).

[h] Most patients would need only one post-hospital visit. A patient with gout or multiple stone recurrence might need two post-hospital visits and additional visits every 6 months.

[i] It is assumed that DRG payment would continue for inpatient facility services.

[j] Packaged payment can include services related to an ambulatory or inpatient episode of care or an ambulatory visit. A total episode-of-care package, though not shown here, would combine services in ambulatory- and inpatient-episode-of-care packages. A special-procedure package, also not shown here, would include services associated with a special procedure such as ESWL.

[k] Capitation payment here includes ambulatory and inpatient services, including physician, ancillary, and hospital services. Capitation payment could alternatively exclude hospital inpatient sevices.

SOURCE: Office of Technology Assessment, 1986 (182). Based on data from A. Jenkins, University of Virginia Medical School, Charlottesville, VA, personal communication, Nov. 26, 1985.

treatment for upper urinary stones among all possible alternatives, including provision in the least costly setting. Capitation payment to providers has been implemented widely in the private sector, including some limited experience with the Medicare population. Capitation payment to fiscal intermediaries (e.g., the Part B Medicare carriers), in which the intermediary would then pay providers for care to beneficiaries, has not been tried (182).

ESWL illustrates several issues regarding Medicare physician payment policies that are distinct from hospital payment issues. Incorporating ESWL into the physician payment system has posed less of a problem than it did with hospital payment, largely because the coding system used to classify and report physician procedures, unlike the hospital coding system, is systematically and annually updated. ESWL already has its own code in this system, the Current Procedure Terminology. But unlike Medicare hospital payment, determining physician payment level is not automatic once classification of a new procedure is made. Determining that level, done autonomously by each carrier, has presented a significant issue that is amplified by the fact that the technology is one that may become cheaper over time for physicians to provide.

HCFA has in fact taken an unusual approach toward establishing appropriate initial physician payment levels for ESWL. As mentioned above, in January 1986, HCFA advised carriers to "consider the time and effort involved in other nonsurgical procedures" when "evaluating and determining a reasonable charge for ESWL" (192). It specifically suggested that carriers pay a global fee for ESWL and associated pre- and posttreatment physician case, and that the ESWL component of this payment might be more appropriately compared to certain urinary radiological procedures than to surgical treatments for urinary stones (192). Addressing the problem more generally, HCFA has recently proposed setting special Part B payment limits for expensive technologies with few suppliers (51 FR 5726).

OTHER PUBLIC PAYERS FOR HEALTH CARE SERVICES

Veterans Administration

VA provides free or subsidized health care services to the eligible proportion of the approximately 30 million veterans of the U.S. Armed Services. Veterans are eligible to receive VA care if they have service-connected disabilities, or if they have nonservice-connected disabilities and are unable to obtain or pay for needed care. VA operates 172 hospitals around the country and treated about 1.25 million acute care patients in 1981. In addition, VA provides a variety of long-term care and ambulatory services (174). With an annual budget of approximately $1.3 billion for medical supplies and equipment, VA represents a substantial market for medical devices (179).

A significant number—about one-fourth—of patients in VA hospitals with a diagnosis of upper urinary stones are spinal cord injury patients (102). VA operates 19 Spinal Cord Injury Centers around the country to provide special, targeted care to this population (180). Spinal cord injury patients tend to form recurring urinary stones because their disability usually prevents normal urination, inviting urinary tract infections and requiring a permanent indwelling catheter (102). Thus, this population has a much higher incidence of stones than does the general U.S. population.

Routine equipment and supplies needed by VA hospitals may be purchased at the local level. The purchase of costly equipment, however, must be reviewed and approved by the VA central office in Washington, DC. A list of "controlled items" for equipment such as X-ray apparatus is maintained by the central office, and purchase of these items requires an evaluation of need. For expensive equipment, such as CT scanners, the VA central office ranks hospitals by perceived level of need and allocates funds separately from the individual hospital budgets. In the case of CT scanners, the VA marketing center purchased several devices at once in order to negotiate a group discount (76). The marketing center purchases CT scanners for other government agencies such as DOD, enabling the center to combine purchases and negotiate quantity discounts from manufacturers.

In June 1983, the Chief Medical Director in the VA central office formed a High Technology Assessment Group to "determine what course the VA should follow with respect to acquisition of major new technology in the future" (168). At the first meeting of this group in 1984, the group was presented with data supporting the purchase of a Dornier lithotripter (102). These data, collected from a survey by the central office's Office of Surgical Services, indicated that 4,800 veterans underwent treatment for upper urinary stones in 1984, that the VA could support the purchase of several lithotripters (102). The Office of Surgical Services has requested two devices to be purchased in fiscal year 1986 and intends to request a third in fiscal year 1987. These lithotripters would be placed in VA hospitals serving a high proportion of spinal cord injury patients, possibly the facilities in Hines, Illinois; Long Beach, California; and Memphis, Tennessee (102).

Meanwhile, arrangements to establish an ESWL facility at the VA hospital in New York City are already in place. This facility is an example of shared provision and use of lithotripsy. A Dornier lithotripter is being purchased by the Paralyzed Veterans of America and donated to the VA hospital. The hospital is providing the facility and funding renovations; a nearby private hospital is funding the staff to run it. The private hospital will refer patients to the facility, although VA patients will have first priority use. The facility is scheduled to become operative by the end of 1986 (102).

VA is a self-contained system that plans and purchases its own equipment and is on a finite budget. This can lead to a small number of ESWL machines at the facilities and in the areas where they will serve the greatest number of patients. A side effect of VA's self-contained system, however, is that VA's placement decisions are isolated from planning decisions made in the community at large. For example, the first ESWL facility at the Bronx VA hospital is in an area already served by one ESWL unit. Of other VA spinal cord injury centers in line for a lithotripter, one is in the Chicago area (where several other facilities are planned in the community) and a second is in the Los Angeles area, which also has several units. There is no routine mechanism through which to share facilities or purchase services between VA and non-VA patients.

Spouses and unmarried children of certain disabled veterans, or survivors of such veterans, are covered under the Civilian Health and Medical Program of the Veterans Administration (186). This health care financing program operates in an identical manner to the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), described below.

Department of Defense

DOD operates military hospitals for use by persons in the U.S. Armed Services on active duty. It also operates CHAMPUS, which pays for much of the health care provided to military families.

CHAMPUS provides payment for medical services to dependents of active duty personnel and to Armed Services retirees, their families, and their survivors. It requires no premiums. All eligible persons may receive any inpatient or outpatient services provided at military hospitals. If they live near a military hospital (within certain zip codes), they must first determine whether services are available for inpatient care at that hospital before seeking care in the community in order to be covered by CHAMPUS. Ambulatory care does not require a predetermination of available services at the military facility. Care at military hospitals is provided on a space available basis. There is no charge for outpatient services received at a military hospital; inpatient services require a very small nominal charge per day (185).

If a CHAMPUS beneficiary does not live near a military hospital, or if the hospital has affirmed that the needed service is not available there, he or she may seek services in the community. In this case, CHAMPUS covers both inpatient and ambulatory services unless the beneficiary is also eligible for Medicare. Inpatient services require a small fee per day or $25 (whichever is more) on the part of active duty families, and a 25 percent copayment of the approved charges on the part of retirees and their families. Ambulatory services require a deductible and a copayment (20 percent of approved charges for active duty families and 25 percent for retirees and their families). Dependent parents and parents-in-law are not covered for community services (185).

Since no military hospitals as yet have ESWL, CHAMPUS pays for the service only in the community. Since there is very little charge history for the procedure, the program is reimbursing physicians for the billed charge until enough bills have been received to permit other calculations of an approved charge (69).

Indian Health Service

IHS, part of the Public Health Service in the U.S. Department of Health and Human Services, provides health care services for Native Americans through its own facilities or through contracted services provided to Native Americans in other facilities. In 1984, IHS operated 47 hospitals, and an additional 4 hospitals were tribal-operated. These hospitals vary greatly in size, but most are small; only four have more than 100 beds (183). There are a number of specialized services not available in any IHS hospital, such as cardiac catheterization, burn care, open heart surgery, and radiation therapy.

In 1984, the IHS service population consisted of approximately 937,000 American Indians and Alaskan Natives, and 102,843 Indian patients were admitted to IHS, contract, or tribal hospitals (194). Services in IHS facilities are provided without charge "to persons of Indian descent belonging to the Indian community served by the local facilities and program" (42 CFR 36). When specialty care is not available in an IHS direct service facility, a patient may be referred to a contract care facility (a physician, hospital, or other provider with whom the IHS has a contract for service to its population). To be eligible for contract care, an individual must be a member of, or closely associated with, a tribe that resides within a designated contract health service delivery area (42 CFR 36).[16] Not all persons that consider themselves Native Americans reside in contract health service delivery areas, and not all that do are eligible for contract care.

Given the size and primary care orientation of IHS hospitals, it is highly unlikely that an ESWL device will be purchased by any of them. If the IHS hospital does not have surgical facilities, and urinary stone patients are referred to a contract hospital, the access of these patients to ESWL will depend on whether the contract hospital has an ESWL unit.

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[16] Indian students, transients, and foster children are also eligible for contract services.

Chapter 7

Effects of Federal Policies on Planning for ESWL

Chapter 7
Effects of Federal Policies on Planning for ESWL

INTRODUCTION

Planning for extracorporeal shock wave lithotripsy (ESWL), whether done on the institutional, local, or regional level, may be affected by Federal policies in two ways. First, to the extent that institutional or local planning is driven by market concerns, it is affected by the Federal payment programs desribed in the previous chapter. Second, ESWL distribution and use may be affected by Federal health planning policies, which operate largely through State certificate-of-need (CON) laws and entail review and approval mechanisms. The Federal Government has been a strong proponent of regional health planning for much of the past decade, although interest has waned in the past few years.

The rationale for planning policies is that they may improve the distribution of major health facilities and equipment for which the market alone does not provide an acceptable solution. Under Medicare cost-based reimbursement for inpatient services,[1] it was hoped that planning policies would curb oversupply of hospital beds and expensive equipment. Hospitals under cost-based reimbursement had a financial incentive to acquire and use expensive technologies, with few countervailing influences. Requiring these facilities to get prior approval for capital expenditures was one potential way to prevent health facilities from acquiring more beds and expensive equipment than was necessary to ensure that sufficient services were available to the local populations.

The State CON programs that have been encouraged by Federal law have not met with unqualified success. In the past few years, representatives of the Federal Government, disillusioned with the inability of planning policies to curb high hospital costs and Medicare expenditures have emphasized payment policies as the mechanism through which to encourage providers to restrain hospital expenditures. But planning laws are still in place in most States, and planning as well as payment policies may have a strong effect on the adoption, diffusion, and distribution of ESWL. Government planning policies may also interact with the activities of providers—particularly hospitals and hospital chains, physician groups, and management companies—to lead to new ways of providing services that have major implications for the availability and distribution of ESWL.

This chapter examines the ways that federally stimulated health planning policies, particularly the CON program, and other less centralized activities are affecting the distribution, cost, and availability of lithotripsy. It then describes the interaction of the formal planning system with the market-based planning activities and the implications of these new organizational arrangements for acquiring and providing ESWL. Finally, it discusses the effects of technological change, including advances in the use of ESWL, on the provision of this technology.

FEDERAL PLANNING POLICY AND THE CON PROGRAMS

The Federal Government has been involved in health care planning for some time, an interest originally arising out of its substantial involvement in financing the expansion of health care facilities (6). Laws passed in the 1960s provided Federal funding to regional health planning agencies to support a variety of planning activities, including the review of projects being evaluated by the fledgling State CON programs (6). The Social Security Amendments of 1972 (Public Law 92-603) extended Federal involvement in local and regional planning through the section 1122 provisions, which authorized the Federal Government to enter into voluntary agreements with States. Under these agreements, Medicare and Medicaid could withhold payment for their depreciation and interest shares of certain capital investments made by health care facilities[2] if State or local health planning agencies did not approve those investments. (Section 1122 does not apply to operating costs.) However, due to limitations in authority and in financial support, these agencies were largely ineffective (6).

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[1] Prior to October 1983, Medicare paid all hospitals on the basis of Medicare's share of the costs of the inpatient services provided in those hospitals. As costs rose, payments rose accordingly.

Congress continued to express its resolve to encourage health planning with the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). This major planning legislation set up a consolidated system of local health systems agencies to plan, State planning agencies to regulate, and State coordinating councils to advise and link the two (6). It also established planning and development grants, and—most importantly—it required that States pass CON laws in order to receive future health-related funds from the Federal Government.[3]

The State CON Programs

CON laws, passed by the individual States, empower State planning agencies to deny reimbursement to hospitals for large capital expenditures unless the agency finds a "need" for the service to be provided. In order to comply with Federal regulations, States must have laws mandating CON review for certain new institutional health expenditures. These laws must include prior approval for all equipment purchases over $400,000 and all new institutional health services with operating costs over $250,000 per year (42 U.S.C. 300). States may have lower but not higher thresholds and remain in compliance with Federal law.

By 1983, all States but one (Louisiana) had CON laws. However, numerous problems have plagued the CON-based planning system since it was instituted in 1974. Observers have suggested that health planning agencies have neither the resources nor the incentives to fully enact their legislative powers (171), and early studies found little effect of CON on hospital investment (74). Also, Federal regulations do *not* require that new equipment acquired by physicians' offices be covered under CON laws, a deficit identified early in conjunction with the diffusion of computed tomography (CT) scanners (175).

The extent to which CON laws are actually effective in reducing unnecessary services (and costs) is still an active subject of debate, and recent Federal funding for the CON-based planning program has stipulated that States not complying with the act not be penalized (179). Consequently, many States' laws are no longer in compliance with Federal thresholds. Table 14 presents the status of laws in each State as of April 1986. As of that time, 11 States had raised one or more of their CON thresholds above the Federal maximum levels, and eight States had no CON laws at all (158).

The Dornier lithotripter, with its cost of about $2 million, exceeds the equipment purchase threshold levels for CON approval in all of the States with CON laws. In many States, the addition of an ESWL unit may be considered a new institutional health service, rendering the unit subject to CON review on the basis of its high operating expenses as well. In 1984, potential ESWL providers in the States with CON laws generated a total of 94 applications for the purchase of extracorporeal lithotripters (78). In the first half of 1985, 175 CON applications for ESWL were received (39), and at least two States (Mississippi and Oklahoma) have developed specific guidelines for ESWL (193).

Because CON review for ESWL may be invoked either on the basis of purchase costs or operating costs, in theory CON laws could de-

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[2] For the purposes of section 1122, "health care facilities" include hospitals, kidney disease treatment centers, skilled nursing facilities, intermediate care facilities, rehabilitation facilities, and ambulatory surgical facilities (42 CFR 100).

[3] Public Law 93-641 stated that if a State had not enacted a CON program by 1979, that State would not receive "any allotment, grant, loan, or loan guarantee, or . . . any contract under this Act, the Community Mental Health Centers Act, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 for the development, expansion, or support of health resources in such State until such time as such an agreement is in effect."

Table 14.—Certificate-of-Need Thresholds in Each State and the District of Columbia, 1986

State	Expenditure threshold requiring approval[a]			Require approval for some physician-owned equipment	Repeal or sunset date	1122 program
	Capital	New health services	Equipment			
Alabama	$ 600,000	$ 200,000	$ 200,000	no	none	no
Alaska	1,000,000	any expenditure	1,000,000	no	none	no
Arizona	—	—	—	—	March 1985	no
Arkansas	600,000	250,000	400,000	no	none	yes
California	1,000,000	certain services	1,000,000	no	January 1987	no
Colorado	2,000,000	1,000,000	1,000,000	yes	indefinite	no
Connecticut	714,000	any expenditure	400,000	yes	none	no
Delaware	150,000	any expenditure	150,000	no	none	yes
Dist. of Col.	600,000	250,000	400,000	yes	none	no
Florida	600,000	250,000	400,000	no	July 1987[b]	no
Georgia	600,000	any expenditure	400,000	no	none	yes
Hawaii	600,000	any expenditure	400,000	no	none	no
Idaho	—	—	—	—	June 1983	yes
Illinois	600,000	certain services	400,000	no	January 1986[b]	no
Indiana	750,000	0	750,000	no	June 1987	yes
Iowa	600,000	250,000	400,000	yes	none	yes
Kansas	—	—	—	—	July 1985	no
Kentucky	600,000	250,000	400,000	no	none	yes
Louisiana	—	—	—	—	Never enacted	yes
Maine	350,000	135,000	300,000	no	none	yes
Maryland	600,000	250,000	licensure	licensure	none	no
Massachusetts	600,000	250,000	400,000	no	none	no
Michigan	150,000	0	150,000	no	none	yes
Minnesota	—	—	—	—	June 1984	yes
Mississippi	600,000	150,000	400,000	no	July 1986	no
Missouri	600,000	250,000	400,000	yes	none	no
Montana	750,000	100,000	500,000	yes	July 1987	no
Nebraska	500,000	250,000	400,000	no	none	yes
Nevada	600,000	250,000	400,000	no	none	no
New Hampshire	600,000	250,000	400,000	yes	none	no
New Jersey	150,000	any expenditure	150,000	no	none	yes
New Mexico	—	—	—	—	June 1983	yes
New York	300,000	any expenditure	300,000	no	none	no
North Carolina	600,000	250,000	400,000	no	none	no
North Dakota	600,000	250,000	400,000	yes	none	no
Ohio	600,000	250,000	1,000,000	no	none	no
Oklahoma	600,000	250,000	400,000	no	1989[b]	yes
Oregon	variable	250,000	400,000	yes	none	no
Pennsylvania	600,000	250,000	400,000	no	none	no
Rhode Island	150,000	75,000	150,000	yes	none	no
South Carolina	600,000	250,000	400,000	no	none	no
South Dakota	600,000	250,000	400,000	no	none	no
Tennessee	1,000,000	any expenditure	1,000,000	no	June 1991[b]	no
Texas	—	—	—	—	September 1985	no
Utah	—	—	—	—	January 1985	no
Vermont	150,000	any expenditure	125,000	no	none	no
Virginia	600,000	any expenditure	400,000	yes	none	no
Washington	1,000,000	500,000	1,000,000	no	none	no
West Virginia	600,000	250,000	400,000	yes	none	yes
Wisconsin	600,000	250,000	600,000	yes	July 1989	no
Wyoming	714,000	150,000	400,000	yes	July 1989	no

[a] Many States have indexed capital and new health services expenditure thresholds to some measure of inflation. Most States with indexing use 1979 as the base year and index according to increases in the composite construction cost index. Most States with a 1979 base year index now have capital expenditure thresholds of $7[illegible],250 and new health services thresholds of $306,750 (158).

[b] Only some portions of the statute are scheduled to sunset.

SOURCE: J.B. Simpson, "Full Circle: The Return of Certificate-of-Need Regulation of Health Facilities to State Control," *Indiana Law Review* 19(4), forthcoming, Summer 1986.

lay or prevent many ESWL purchases in States that have such laws. However, if new, cheaper machines are approved for marketing, they may not require CON approval in States that exceed the Federal equipment threshold unless they are considered new health services.

Nearly all States with CON laws require review of new health facilities, including ambulatory surgical centers (158). However, ambulatory ESWL may be exempt from CON laws if a center offering only ESWL is not considered a surgical center under that State's laws. California, for example, requires CON review of ambulatory surgical centers (94), yet the first Dornier lithotripter in northern California was installed in a free-standing ambulatory center without undergoing CON approval for either the facility or the equipment (68). As demonstrated in table 14, only 15 States require licensure or CON review of equipment that may be used for persons who are not patients of a health care facility (158).

In States with weak or absent CON laws, it is possible that the section 1122 process, which allows Medicare and Medicaid to refuse to pay their share of the capital costs of major equipment whose purchase is not approved by a State agency, may again have some effect. Without a CON process, Medicare and Medicaid may choose to refuse to pay their share of the capital costs of ESWL for patients treated in unapproved facilities in those States that have a section 1122 agreement with the Federal Government. If this should occur, and if some facilities refused to treat Medicare and Medicaid patients as a result, these patients might be required to travel further for treatment. Those close facilities that consequently treat a smaller caseload might also have higher average costs as a result. At present, the section 1122 program is based on voluntary State participation, so it is likely to be a factor only in the four States with a section 1122 agreement but no CON program. However, if Congress does not pass legislation incorporating capital expenses into the Medicare prospective payment system, section 1122 participation will become effectively mandatory in every State (42 U.S.C., 1395).

The Effects of CON and State Health Planning Systems

CON laws appear to be influencing the growth of new arrangements for purchasing, sharing, and providing ESWL in two ways. First, they may be encouraging the movement toward the provision of sophisticated services, such as ESWL, in ambulatory settings. Second, they appear to be encouraging, at least in a few States, the joint purchase of ESWL units by hospitals, physician groups, and management companies.

As they exist in most States, CON laws offer an incentive for health care providers to provide certain very expensive technologies out of the hospital altogether in order to avoid the time and expense (and possible rejection) of CON review. This incentive may have affected the service setting of both CT and MRI. Four years after their introduction into the United States, 18 percent of CT scanners were located in ambulatory facilities. Thirty-nine percent of MRI equipment were located in ambulatory facilities after an equivalent period of time (169). Free-standing imaging centers have emerged as an increasingly common phenomenon around the country (64). ESWL appears to be moving towards a similar diffusion pattern that will include an increasingly large number of free-standing ESWL centers as well as an emphasis on outpatient ESWL at many hospitals.

Shared purchase of major equipment among several hospitals or physicians has become a recently familiar theme in health care (96), and ESWL exemplifies a diverse array of such shared purchase arrangements. In Washington, DC, for example, three hospitals are copurchasing a lithotripter that is sited at one of the hospitals (60). In Cleveland, Ohio, two hospitals planned joint purchase of a lithotripter, sited in a separate facility, in order to share expenses and speed CON approval (56,113). In Memphis, Tennessee, six hospitals and a group of urologists have created a for-profit company to purchase a lithotripter that will be located at the University of Tennessee Medical Center if the project receives CON approval (123). The ambulatory lithotripsy center in Los Gatos, California, is jointly owned by several hospitals, urologists, and Uro-Tech Management Corp. (86).[4] In Dallas, Texas, several hospitals and urologists are planning joint establishment of a lithotripsy center for the International Biomedics lithotripter, currently under development, to be installed when it begins clinical trials (127).

Although CON laws (and their administration) appear to be encouraging some of these joint purchasing arrangements, the two do not necessarily coincide. Planners in southwestern Pennsylvania, for example, have attempted to encourage such shared purchase but have been unable to do so (36). Instead, this planning agency must attempt to set priorities for ownership of ESWL units among individual hospitals. The Health Planning Council of Greater Boston has similarly relied on setting priorities for acquisition. This planning agency, which produced the first thorough planning study for ESWL in the United States, determined that in the short run there existed a need for only one lithotripter in the area served by that planning agency, and that the hospital operating the unit would serve as a referral center for other hospitals in the area. Permission was granted to Massachusetts General Hospital to house the lithotripter, and that hospital became one of the six investigational sites in the United States to obtain Food and Drug Administration approval for ESWL. A second Boston area hospital has since received approval for and installed a machine (48,125).

In some areas limited joint purchase and shared use are not enough to obtain CON approval. The Virginia Department of Health rejected a proposal to locate an ESWL unit in the Virginia suburbs of Washington, DC, even though the unit was to be jointly purchased by two area hospitals and a group of area physicians and located at a large suburban teaching hospital (140). The justification for rejecting the proposal was that the proposed service area of 1.5 million population was not sufficient to support a extracorporeal lithotripter, especially since it was likely that one or more lithotripters would eventually be located in Washington, DC, itself (141). The Virginia Department of Health's rationale has since been supported by the fact that three Washington, DC, hospitals have received permission from the District planning agency to jointly acquire an ESWL unit, and the fact that hospitals in several nearby Maryland suburbs are considering ESWL purchases (51). Maryland requires licensure, but not CON approval, for major medical equipment.

A contrasting example is set by Chicago, in which numerous ESWL units may exist almost side by side. Two hospitals in Chicago already have approval for ESWL. One of these, Michael Reese Hospital, is a testing site for Medstone's ESWL device. The Chicago Health Systems Agency has recommended further approval for extracorporeal lithotripter purchases by three other major Chicago hospitals (all associated with universities), for a potential total of five devices in the metropolitan area (56). Finally, the Veterans Administration plans to install an ESWL unit at one of its hospitals in the Chicago area (102), a decision outside the control of the planning agency.[5] Thus, it is conceivable that six ESWL units could compete for patients within the same metropolitan area.

These examples illuminate the fact that generalities regarding the overall impact of CON laws on the diffusion and distribution of ESWL are difficult to make. In a few States, the planning process seems to be encouraging joint purchase of ESWL and may restrict the number of devices below the number that would have been acquired were there no planning laws. In other States, however, even those with fully functional CON laws, planning seems to be having no restrictive effect whatsoever. For the United States as a whole, it is unlikely that planning laws will restrain ESWL purchases below the numbers that various organizations have estimated would be sufficient (see ch. 5). The Blue Cross and Blue Shield Association, for instance, has suggested that the entire U.S. population could be adequately served by 50 ESWL units (14). But Dornier had 50 ESWL units installed in the United States by the end of 1985 and plans to have 100 in place by the end of 1986 (125). The existence of planning laws seems highly unlikely to restrict the overall number of devices to a minimum level.

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[4] Uro-Tech, a private management company, holds partial ownership in a number of ESWL units, including the first three lithotripters located in free-standing ambulatory care centers (in California, North Carolina, and Florida) (41).

[5] Under Public Law 93-641, the National Health Planning and Resources Development Act of 1974, the VA was given voting membership on State health coordinating councils and on regional health systems agencies. A VA hospital was supposed to submit an application to the health systems agency for new construction or equipment. The agency made a recommendation to the VA Central Office, which could approve or disapprove without regulatory constraint and did not have to explain its action" (180). VA's participation in the health planning process is voluntary, and State planning councils have no authority to disapprove the installment of an ESWL unit in a VA facility.

A contrast to the U.S. planning experience with ESWL is provided by Australia. About 80 percent of acute health care in that country is provided in public hospitals, and expensive technology acquired by those hospitals must be approved and financed through the state governments (148). The Australian Department of Health's National Health Technology Advisory Panel has produced a full assessment of ESWL to assist the states in planning for the technology. The panel concluded that although the technology is "more expensive than percutaneous stone removal it appears to involve less cost than open surgery and offers significant patient benefit compared with both of these alternatives" (38). The panel estimated the number of eligible patients with upper urinary stones in each state in the Commonwealth of Australia and concluded that Australia had an annual demand for ESWL of 2,500 to 3,000 patients. Based on this figure and a target caseload of 1,200 to 1,400 patients per machine per year, the Panel concluded that (38):

> On the basis of current numbers of procedures for upper urinary tract stones, not more than three ESWL machines would be needed for Australia, two of which should be located in Sydney and Melbourne. However, geographical factors may result in a need for additional machines. The machines should be sited in hospitals which have well developed urology and radiology departments, with appropriate access to percutaneous (PCN), surgical and transurethral procedures.
>
> The number of machines required should be kept under review in the light of the length of time patients must wait for treatment and future technical developments. Availability of second generation equipment may became a significant factor in the medium term and could influence decisions of procurement of a third machine.

PLANNING AND THE DYNAMIC MARKET

Planning for ESWL, as with most technologies, is complicated by the existence of a dynamic market. In this case, the market is changing on five fronts:

1. technologies to reduce the recurrence of urinary stones, and consequently the overall incidence of stones;
2. improvements in invasive treatments for urinary stones;
3. the emergence of competing manufacturers of ESWL equipment;
4. experience in the most appropriate role for ESWL; and
5. modifications in the Dornier lithotripter to extend its uses.

Technologies to reduce the incidence of urinary stones among those people with frequently recurring stones are an important unknown in the stone treatment market. These technologies may be small in number and effect, or they may exert an important influence on the population. In the extreme, if preventive measures were successful, a significant proportion of second stones could be prevented, and the total number of patients needing treatment for problematic stones could be substantially reduced. Under the latter scenario, those patients who did have stones would likely be having their first experience with this problem, and they would be at less of a risk for untoward outcomes associated with invasive procedures. This consideration might affect decisions regarding which treatments were most appropriate; fewer patients might be referred to ESWL out of a fear that multiple surgeries might endanger the kidney. Urologists disagree over whether preventive medications such as potassium citrate can prevent more than a small proportion of stones in the immediate future. Still, such medications remain a highly important treatment for study that may be both effective and cost savings for certain patients.

Improvements in current invasive alternatives to ESWL, particularly percutaneous removal of stones, may have a much larger and more immediate effect. In centers in which percutaneous lithotripsy is performed on high volumes of patients, by surgeons with sufficient experience and expertise, this procedure may be very comparable to ESWL in cost and clinical appropriateness. Percutaneous lithotripsy will have particular appeal to those urologists who do not have access themselves to ESWL and to hospitals who cannot justify or afford ESWL equipment. A danger of the appeal of percutaneous lithotripsy is that the lower costs, higher success rates, and broader use demonstrated by urologists performing this procedure in higher volumes may not be attained by less experienced operators in less efficient settings. Also, urologists without access to ESWL may be reluctant to refer patients to a urologist who does perform ESWL unless those patients are clearly unsuitable for more invasive procedures. If existing trends continue and percutaneous lithotripsy proves to be clinically and financially competitive with ESWL when performed by most physicians in most hospitals, the use of ESWL might decline despite the existing fixed costs of expensive equipment already in place.

In contrast to the above scenario, the existence of competing manufacturers for ESWL could dramatically expand the use of this technology. It is the high cost of ESWL equipment that draws the attention of third-pary payers, causes ESWL to come under the jurisdiction of CON laws, and invites the scrutiny of planners where anticipated caseloads of equipment to be purchased are small. Competing manufacturers are emphasizing the lower cost of their equipment, which might justify the existence of many more machines. However, the competing lithotripters are not yet clinically proven, and their actual costs cannot be judged until these devices have been installed and used on a number of patients. The competing device apparently closest to marketing in the United States, the Medstone lithotripter, had treated only four human patients as of the end of 1985 (4). Thus, this device is unlikely to be available for general marketing before the end of 1986, even if it proves to be clinically effective.

Experience in the most appropriate uses of ESWL, both current and future models, is an important area of investigation, especially in light of the rapid evolution of percutaneous stone removal. Increased understanding of the limits of ESWL might lower its use relative to percutaneous procedures. Conversely, increased appreciation of its possibilities for treating difficult stones when used in combination with percutaneous and transurethral procedures may increase the use of ESWL.

Finally, the market for ESWL could be greatly expanded if the technology itself is extended to other uses. If protocols involving the use of ESWL on lower urinary stones, such as the one being conducted at the University of Virginia, are successful, the possible uses of ESWL will expand still further. An even more dramatic expansion of the technology is its application to gallstones, which afflict a larger number of patients in the United States than do upper and lower urinary stones combined (124).[6] Extending ESWL applications to gallstones does not necessarily mean that both gallstones and urinary stones could be treated on the same machine. At present, a separate ESWL device specific to gallstones is a more realistic possibility; a gallstone lithotripter currently under development by Dornier has been tested on several patients in West Germany, with some success (147). It is not likely to reach clinical trials in the United States for at least a year (125). Still, if ESWL for gallstones became a reality in the near future, it might provide justification for ESWL, in some form, in most major population centers.

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[6] In 1983, 482,000 people were discharged from U.S. non-Federal acute care hospitals with a diagnosis of gallstones, compared with 330,000 people with a diagnosis of kidney and ureter stones and 18,000 people with lower urinary stones (124).

Appendixes

Appendix A

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Appendix B

ESWL: Technical Background

Shock Waves

The Dornier extracorporeal shock wave lithotripter relies on the fundamental properties of shock waves to function. Shock waves are characteristic of explosions and of supersonic flow of air over a body, such as a jet. In ESWL, the source of the explosion is an electrode which produces a spark. The mini-explosion produces an instant rise in temperature and pressure in the fluid immediately around the source of the spark, causing the fluid to expand at supersonic speed. A blast wave forms from this point, carrying the excess energy from the point of the explosion to distant parts of the fluid (154).

Unlike sound waves, such as ultrasound waves, shock waves are not sinusoidal periodic oscillations. Instead, a graph of pressure vs. time shows a shock wave as a single distinct peak that gradually decays. This wave loses its energy less quickly if it travels through an uninterrupted medium than an interrupted one. Thus, the Dornier lithotripter employs a water bath, so that the wave travels directly from the water to the soft tissues of the body, which have similar acoustic properties. Developers of other lithotripters, such as the Medstone lithotripter, are experimenting with a fluid-filled belt rather than an open bath.

To focus the wave on the stone, the lithotripter uses a semi-ellipsoidal reflector around the tip of the electrode. The spark is generated at the focal point (f1) of the reflector. The shock wave produced spreads in a circular form, like a pebble dropped in a pond, until it reaches the ellipsoidal wall. Each point of the ellipsoid wall becomes a generating point for a new circular wave. These wave fronts move outward again until they convene simultaneously at the second focal point (f2). The stone is positioned at this second focal point, the point of greatest force (22).

At the interface of the tissue and the stone, there is a large difference in acoustic impedance. A large pressure zone is created as the shock wave passes from the tissue to the stone, and in this zone, the pressure exceeds the strength of the stone material and causes it to fragment and break. With the application of repeated shock waves, the stone can be broken into small fragments of less than 2 mm that can pass through the urinary tract with the urine (187).

To ensure maximum efficiency for transmission of the shock wave, the water in the water bath must be treated. The Dornier lithotripter includes a water treatment sytem that softens, degasses, and regulates the temperature of the water as it is exchanged between the treatment of each patient. The water softening system removes soluble impurities from the water, which purifies the water and adjusts its electrical conductivity. The water degassing unit removed dissolved gas and bubbles in the water to ensure efficient wave transmission. The water temperature is kept near body temperature for the comfort and safety of the patient (187).

The Shock Wave Generating System

The shock wave in the Dornier lithotripter is generated by a spark from an underwater electrode. The electrode has a positive and a negative point, is connected to a high-voltage generator, and is located at the first focus of the brass semi-ellipsoid shell. When the electrode is charged by the generator, it produces a brief (1 microsecond) spark caused by the electrical current across the electrode. The generator can be adjusted to produce power ranging from 18,000 to 24,000 volts (137). Thus, the strength of the treatment can be varied in two ways: by the number of shocks given (as few as 500 to as many as 2,500 or more), and the force of the shocks, which varies by the voltage.

The generator is coupled to an electrocardiogram, which synchronizes the shock wave with the patient's heart beat. The voltage generator can only be activated when the heart is contracting and is refractory to external stimuli (the time after the QRS peak in the electrocardiogram recording) (187).

An electrode is not the only possible method of producing an extracorporeal shock wave. A laser is another potential form of energy that can produce the mini-explosion that, in turn, produces the shock wave. At least one American firm, International Biomedics, is developing a laser-driven lithotripter (172). Its potential benefits include a cheaper source of energy; the present electrodes used in the Dornier lithotripter cost $180 or more apiece, and a single treatment may use two or three electrodes.

The Stone Location System

The Dornier lithotripter uses fluoroscopic (X-ray) imaging to locate the stone. Since the second focus of the ellipsoid, where the shock waves converge, is only a 1.5 cm^3 area, efficient destruction demands that the stone be pinpointed accurately. The Dornier device includes two independent X-ray systems positioned so that their beams cross. The patient is adjusted, using a mechanical positioning system, until the stone to be fragmented lies at the point of this intersection. At any time during the procedure, the lithotripsy operator can activate the X-ray scanning system briefly and get an updated picture of the stone (22). If the stone has moved in the course of the treatment, as it frequently does, the patient can be immediately adjusted so that the stone again lies at the intersecting point, and treatment can continue.

During the development of the device, Dornier experimented with ultrasound imaging to locate the stone. A major advantage of ultrasound is its safety relative to fluoroscopy, since it does not produce ionizing radiation. However, Dornier was unable to develop a system that could image the stone adequately for precise location purposes (22). Dornier itself is still investigating the potential of ultrasound imaging (126), and at least two other ESWL developers (Northgate and EDAP) are also experimenting with ultrasound (153).

Patient Preparation

Many of the patient preparations associated with surgery are not necessary for ESWL. Patients may be given a laxative before treatment to eliminate any intestinal gas, which can interfere with the location of the stone during the procedure (24). Anesthesia is necessary, although either regional or general anesthesia can usually be used; preferences vary by center. In the first six U.S. hospitals with ESWL, as of May 1985, approximately 47.5 percent of patients had undergone regional (spinal or epidural) anesthesia, and the remaining 52.5 percent had undergone general anesthesia (11). Preferences among centers varied considerably, however; use ranged from only 10 percent general anesthesia at Charlottesville to 100 percent general anesthesia at Gainesville (11). The option of using regional rather than general anesthesia is one of the factors that increases the safety of ESWL relative to open surgery for certain patients.

Some patients, such as those with staghorn or ureteral stones, require adjunct procedures before or after ESWL. Ureteral stones, for example, can be manipulated up into the pelvis of the kidney before ESWL treatment, where there is more space for the stone to break up (105). In these patients, catheterization before ESWL treatment is often performed in an attempt to move the stone into the kidney. Patients with infected stones also require some additional pretreatment preparation, such as the administration of antibiotics 1 or 2 days before treatment (24). Finally, patients with stones of insufficient contrast density to be visualized adequately on X-rays may require the injection of a contrast medium before the procedure (24).

Appendix C

Coding Systems

The CPT-4 Coding System for Physician Services

Two widespread systems for codifying medical diagnoses and procedures exist in the United States: the Physicians' Current Procedural Terminology, Fourth Edition (CPT-4), which codes procedures performed by physicians, and the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), which codes hospital diagnoses and procedures (9,188).

CPT-4 is a detailed list of five-digit codes for physician services, organized according to organ systems, that was developed (and is maintained) by the American Medical Association (AMA). It was initially developed to facilitate physician reporting on claim forms, and Medicare recently began requiring that physician bills be based on a version of this system. CPT has undergone numerous expansions, and the number of codes increased from 2,084 in 1966 to 7,040 in 1985 (182).

These codes may be clarified with modifiers under certain circumstances. For example, the CPT-4 manual states:

> [Certain procedures are a combination of a physician component and a technical component. When the physician component is reported separately, the service may be identified by adding the modifier '-26' to the usual procedure number or the service may be reported by use of the five digit modifier code 09926 (10)].

This reporting procedure is the mechanism through which a radiologist, for example, may get paid a "professional component only" charge for interpreting an X-ray in a hospital and a total charge (including an implicit or explicit "technical fee") for an office-based X-ray, where the equipment is owned by the physician.

Because CPT-4 is entirely under the aegis of AMA and is updated annually, the advent of extracorporeal shock wave lithotripsy (ESWL) created no structural difficulties for this coding system. A new code to represent ESWL performed by a physician, 50590, has been created.

The ICD-9-CM Coding System for Hospitals[1]

The diagnosis-related groups (DRGs) used by Medicare's prospective payment system to categorize patients for reimbursement purposes are based on a coding system known as ICD-9-CM. This system has two parts. The first and largest part is a comprehensive list of diseases with corresponding codes. It is compatible with the World Health Organization's (WHO's) list of disease codes, maintained for statistical purposes, and is updated along with the WHO list every 10 years. The second part of ICD-9-CM contains procedure codes. These are independent of the disease codes and are not directly based on an international system, although in the past they have been revised concurrently with the disease codes. The National Center for Health Statistics is the official WHO coding liaison in the United States, but the development and maintenance of the American version of ICD has historically been a cooperative effort of representatives from a variety of governmental agencies and professional organizations (70). The codes have historically been infrequently updated, and until very recently there was no established formal procedure for interim addition of codes or assignments of new diseases and procedures to existing codes. In late 1985, as a result of the dilemmas and uncertainties arising out of coding and DRG classification, a formal ongoing coding recommendations task force, jointly chaired by the National Center for Health Statistics and Health Care Financing Administration and including representatives of the major interested organizations, was established (50 FR 24374).

The ICD-9-CM codes are organized according to organ system (circulatory system, digestive system, etc.), with additional sections for subjects such as infectious diseases and accidental injury. Diseases are assigned three-digit codes, with fourth and occasionally fifth digits available to allow more specificity. For instance, hereditary anemia is code 282. Sickle-cell anemia, one type of hereditary anemia, is code 282.6, and the particular form called sickle-cell/Hb-C disease is further specified as code 282.63. The procedure codes are organized in a fashion similar to the disease codes, except that maximium specificity is reached at four digits rather than five. Table C-1 lists some ICD-9-CM codes relating to urinary stones.

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[1] Portions of this section are exerpted from U.S. Congress, Office of Technology Assessment, *Medicare's Prospective Payment System: Strategies for Evaluating Cost, Quality, and Medical Technology*, OTA-H-262 (Washington, DC: U.S. Government Printing Office, October 1985).

The process of DRG assignment depends on both the diagnosis and procedure codes. The code for the principal diagnosis places the patient in a major diagnostic category and indicates which of several DRGs might be appropriate. The code for the principal procedure (or its absence) is used to determine whether the appropriate DRG is a medical or a surgical one. Surgical DRGs generally have higher reimbursement rates than medical ones. The final choice of DRG then depends on the specific procedure performed, the patient's age, and the presence or absence of coexisting diseases and complications.

The ICD-9-CM coding system, designed for clinical and statistical purposes, presents several problems when used as a basis for reimbursement (70,80,164). First, if inaccurate or inadequate coding was frequent when the DRGs were designed, many hospital cases may have been inaccurately classified. If this is the case, the DRG weights may consequently be inaccurate themselves. Second, some medical conditions can be described by more than one diagnostic code (80). Although any of several diagnoses may be technically correct, their associated codes lead to different DRGs with different weights.

A third major concern regards the procedure codes. Procedures utilizing new technologies may not be appropriately described by any of the current codes, and confusion about which code to use can lead to wide variation in DRG assignment. The code that seems most applicable may lead to an apparently inappropriate DRG; conversely, a DRG with an apparently appropriate reimbursement rate may be based on codes entirely unfitting to the new technology. Coding consultants at the American Hospital Association and the Commission on Professional and Hospital Activities help to reduce confusion and promote coding uniformity. Major problems of coding assignment are now the responsibility of the newly organized task force.

Table C-1.—ICD-9-CM Codes Relating to Urinary Stones

Diagnostic codes:		
592	*Calculus (stone) of kidney and ureter*	
592.0	Calculus of kidney	
592.1	Calculus of ureter	
592.9	Urinary calculus, unspecified	
594	*Calculus (stone) of lower urinary tract*	
594.0	Calculus in diverticulum of bladder	
594.1	Other calculus in bladder	
594.2	Calculus in urethra	
594.8	Other lower urinary tract calculus	
594.9	Calculus of lower urinary tract, unspecified	
Procedure codes:		
55	*Operations on kidney*	
55.0	Nephrotomy and nephrostomy	
	55.01	Nephrotomy (includes removal of stones from kidney)
	55.02	Nephrostomy
55.1	Pyelotomy and pyelostomy	
	55.11	Pyelotomy (includes removal of stones from renal pelvis)
	55.12	Pyelostomy
55.9	Other operations on kidney	
	55.99	other
56	*Operations on ureter*	
56.0	Transurethral removal of obstruction from ureter and renal pelvis	
56.2	Ureterotomy (includes removal of ureter stone through incision)	
57	*Operations on urinary bladder*	
57.0	Transurethral clearance of bladder	
57.1	Cystotomy	
	57.19	Other cystotomy (includes removal of bladder stone through incision)
58	*Operations on urethra*	
58.0	Urethrotomy (includes removal of stone in urethra through incision)	
58.6	Dilation of urethra (includes removal of calculus without incision)	
59	*Other operations on urinary tract*	
59.9	Other operations on urinary system	
	59.95	Ultrasonic fragmentation of urinary stones
	59.99	Other

Appendix D

Glossary of Terms and Acronyms

Glossary of Terms

Access: Potential and actual entry into the health care system.

Ambulatory services: Medical services provided to patients who are not hospitalized.

Ancillary services or technology: Medical services or technology used directly to support basic clinical services, including diagnostic radiology, radiation therapy, clinical laboratory, and other special services.

Approved charge (Medicare): An individual charge determination made by a Medicare carrier on a covered Part B medical service or supply. In the absence of unusual medical circumstances, it is the lowest of: 1) the physician's or supplier's customary charge for that service, 2) the prevailing charge for similar service in the locality (adjusted if necessary by the Medicare Economic Index), 3) the actual charge made by the physician or supplier, and 4) the carrier's private business charge for a comparable service. Also called "allowed charge" or "reasonable charge."

Bladder: See *urinary bladder*.

Capitation payment method: A method of paying for medical care by a prospective per capita payment that is independent of the number of services received.

Carrier (Medicare): Organizations, typically Blue Shield plans or commercial insurance firms, under contract to the Health Care Financing Administration for administering Part B of the Medicare program. Their tasks include computing reasonable charges for physician services, making actual payments, determining whether claims are for covered services, denying claims for noncovered services, and denying claims for unnecessary use of services.

Case mix: The relative frequency of admissions of various types of patients, reflecting different needs for hospital resources. There are many ways of measuring case mix, some based on patients' diagnoses or the severity of their illnesses, some on the utilization of services, and some on the characteristics of the hospital or area in which it is located.

Catheter: A tubular instrument, often with specially designed tips, used for discharging fluids or for distending a passage. A catheter is frequently placed in the urinary tract of patients with stones to aid in the passage and discharge of urine, stone fragments, or small whole stones.

Certificate-of-need (CON): A regulatory planning mechanism required by the National Health Planning Resources Development Act of 1974 (Public Law 93-641) to control expenditures for and distribution of expensive medical care facilities and equipment. CON applications by institutions are reviewed by local health systems agencies, who recommend approval or disapproval; they are denied or approved by State health planning and development agencies.

Coinsurance: That percentage of covered hospital and medical expenses, after subtraction of any deductible, for which an insured person is responsible. Under Medicare Part B, after the annual deductible has been met, Medicare will generally pay 80 percent of approved charges for covered services and supplies; the remaining 20 percent is the coinsurance, which the beneficiary pays.

Colic: Severe pain.

Coverage (Medicare): In the Medicare program, coverage refers to the benefits available to eligible beneficiaries and can be distinguished from payment, which refers to the amount and methods of payment for covered services.

Current Procedure Terminology, Fourth Revision (CPT-4) Coding: A taxonomy of procedures performed by physicians that is used for recording and billing for service rendered. This taxonomy has been incorporated in the HCFA Common Procedure Coding system, which all Medicare carriers are now required to use.

Customary charge (Medicare): In the absence of unusual medical circumstances, the maximum amount that a Medicare carrier will approve for payment for a particular service provided by a particular physician practice.

Customary, prevailing, and reasonable charges: The method used by Medicare carriers to determine the approved charge (see definition) for a particular Part B service from a particular physician or supplier.

Deductible: An initial expense of a specified amount of approved charges for covered services within a given time period (e.g., $75 per year) payable by an insured before the insurer assumes liability for any additional costs of covered services. The Medicare Part B deductible is the portion of approved charges (for covered services each calendar year) for which a beneficiary is responsible before Medicare assumes liability.

Diagnosis-related groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are the case-mix measure mandated for Medicare's prospective hospital payment system by the Social Security Amendments of 1983 (Public Law 98-21).

Fee-for-service payment: A method of paying for medical care in which each service performed by an individual provider can bear a related charge.

Fee schedule: An exhaustive list of physician services in which each entry is associated with one specific monetary amount representing the approved payment for a given insurance plan.

Hematuria: The discharge of blood in the urine.

Idiopathic: Of unknown origin.

Incidence: The number of newly diagnosed cases of a condition over a specified period of time, usually a year.

Inpatient services: Services provided to patients who are hospitalized.

Intermediaries (Medicare): Organizations, typically Blue Cross plans or commercial insurance firms, under contract to the Health Care Financing Administration for administering Part A of the Medicare program. Their tasks include determining reasonable costs for covered items and services, making payments, and guarding against unnecessary use of covered services for Medicare Part A payments. Intermediaries also make payments for home health and outpatient hospital services covered under Part B.

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Coding: A two-part system of coding patient medical information used in abstracting systems and for classifying patients into DRGs for Medicare. The first part is a comprehensive list of diseases with corresponding codes compatible with the World Health Organization's list of disease codes. The second part contains procedure codes, independent of the disease codes.

Lithotripsy: Stone destruction.

Lithotripter: An instrument that fragments, erodes, or otherwise destroys stones in the body.

Medical technology: The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and support systems within which such care is provided.

Nephrectomy: The surgical removal of part of the kidney.

Nephrolithotomy: The surgical removal of a stone from the kidney.

Nephrotomy: A surgical incision into the kidney.

Nephrostomy: The establishment of a passageway through the body to the kidney.

Opportunity cost: In economics, defined as the return available from the best alternative use of a particular resource, for example, the value of the other products that might otherwise have been produced by the resources used in the production of a particular good or service. Any single opportunity taken will have a cost in terms of an opportunity forgone.

Part A (Medicare): Medicare's Hospital Insurance program, which provides insurance benefits against the costs of hospital and related posthospital services for elderly and disabled beneficiaries. Part A, which is an entitlement program for those who are eligible, is available without payment of a premium, although the beneficiary is responsible for an initial deductible or copayment for some services. Those not automatically eligible for Part A may enroll in the program by paying a monthly premium.

Part B (Medicare): Medicare's Supplementary Medical Insurance program, which provides insurance benefits for medically necessary physician services, hospital outpatient services, outpatient physical therapy and speech pathology services, comprehensive rehabilitation facility services, and various other limited ambulatory services and supplies such as prosthetic devices and durable medical equipment. Part B also covers home health services for those Medicare beneficiaries who have Part B coverage only. Part B is optional and requires payment of a monthly premium. The beneficiary is also responsible for a deductible and a coinsurance payment for most covered services.

Percutaneous: Literally, "through the skin"; refers to a surgical procedure that requires only a very small incision. In percutaneous nephrostolithotomy, a kidney stone is removed through a small incision and a channel to the stone, with endoscopic assistance, rather than through a large incision.

Prevailing charge (Medicare): In the absence of unusual medical circumstances, the maximum amount a Medicare carrier will approve for payment for a particular service provided by any physician practice within a particular peer group and locality. Generally, this amount is equal to the lowest charge in an array of customary charges that is high enough to include 75 percent of all the relevant customary charges.

Prospective payment: Payment for medical care on the basis of rates set in advance of the time period in which they apply. The unit of payment may vary from individual medical services to broader categories, such as hospital case, episode of illness, or person (capitation).

Prospective Payment Assessment Commission

(ProPAC): A commission established by the same law that created the DRG-based prospective payment system for Medicare (Public Law 98-21) to make recommendations to the Secretary of Health and Human Services on the annual update factor and on adjustments of DRG classifications and weights.

Pyelolithotomy: The surgical removal of a stone from the renal pelvis.

Quality of care: The degree to which actions taken or not taken maximize the probability of beneficial health outcomes and minimize risk and other untoward outcomes, given the existing state of medical science and art.

Reasonable and necessary services (Medicare): Criteria used to determine what services are eligible for Medicare reimbursement. For some services, HCFA specifically allows or denies coverage; for other services, Medicare carriers and intermediaries themselves determine coverage policy.

Reasonable charge: See *approved charge.*

Renal: Pertaining to the kidney.

Renal calix: One of the finger-like projections of the renal pelvis that collect filtered urine and channel it into the kidney's core.

Renal pelvis: The hollow core of the kidney.

Staghorn stone: A large kidney stone that fills several calices, giving it a dramatic "staghorn" appearance in X-rays.

Struvite stone: A urinary stone composed of magnesium ammonium phosphate and associated with urinary tract infection.

Third-party payment: Payment by a private insurer or government program to a medical provider for care given to a patient.

Transurethral: Through the urethra. Refers to treatment procedures that use instruments passed up the urinary tract, rather than through a surgical incision.

Ureter: One of the two tube-like structures that carry urine from the kidneys to the bladder.

Ureterolithotomy: The surgical removal of stones from the ureter.

Urethra: The structure through which urine passes from the bladder out of the body.

Urinary bladder: The structure that collects urine from the ureters and stores it until urination.

Urinary tract: The organ system that consists of the kidneys, ureters, bladder, and urethra.

Glossary of Acronyms

AHA —American Hospital Association
ALOS —average length of stay
AMA —American Medical Association
AMI —American Medical International
ASC —ambulatory surgical center
AUA —American Urological Association
CFR —Code of Federal Regulations
CHAMPUS—Civilian Health and Medical Program of the Uniformed Services (DOD)
CON —certificate of need
CPHA —Commission on Professional and Hospital Activities
CPT —current procedural terminology
CT —computed tomography
DOD —Department of Defense
DRG —diagnosis-related group
DHHS —Department of Health and Human Services
ESWL —extracorporeal shock wave lithotripsy
FDA —Food and Drug Administration
FR —Federal Register
HCA —Hospital Corporation of America
HCFA —Health Care Financing Administration (DHHS)
ICD-9-CM —International Classification of Diseases, 9th Revision, Clinical Modification
IDE —investigational device exemption
IHS —Indian Health Service
MRI —magnetic resonance imaging
NCHS —National Center for Health Statistics
NME —National Medical Enterprises
OHTA —Office of Health Technology Assessment (Public Health Service)
PPS —prospective payment system
ProPAC —Prospective Payment Assessment Commission
R&D —research and development
VA —Veterans Administration
VHA —Voluntary Hospitals of America
WHO —World Health Organization

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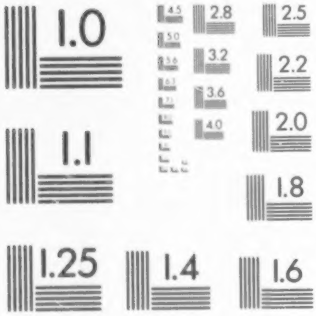
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